UNIVERSIDAD POLITÉCNICA DE MADRID

**ESCUELA TÉCNICA SUPERIOR DE INGENIEROS DE
TELECOMUNICACIÓN**

**A TECHNOLOGICAL FRAMEWORK BASED ON
AUTOMATIC MESSAGING FOR IMPROVING
ADHERENCE OF DIABETIC PATIENTS**

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It is difficult for science and technology, in general lines, to exceed the fiction. But in many, small and unexpected details there will always be absolute surprises that science fiction writers have never thought.

Isaac Asimov

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List of Acronyms

AARP	American Association of Retired Persons
ADA	American Diabetes Association
ADS	Appraisal of Diabetes Scale
AFM	Automatic Feedback Messages
AFM PRO	AFM Professional module
AGP	Adoption of Good Practices
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
API	Application Programming Interface
ASF	Apache Software Foundation
AVAD	Años de Vida Ajustados por Discapacidad
B1	Baseline 1
B2	Baseline 2
BA	Behavioural Analysis
BAN	Body Area Network
BLT	Behavioural Learning Theory

BMI	Body Mass Index
BP	Blood Pressure
BPDI_TA	Blood Pressure Diastolic Treatment Adherence
BPSY_TA	Blood Pressure Systolic Treatment Adherence
BUN	Blood Urea Nitrogen
CD	Chronic Disease
CDS	Clinical Decision Support
CGM	Continuous Glucose Monitoring
CGMS	Continuous Glucose Monitoring System
CHO	Carbohydrate
CI	Confidence Interval
CIS	Computer Information System
CPS	Control Preferences Scale
CT	Computerized Tomography
DALYs	Disability-adjusted life year
DB	Database
DKA	Diabetic Ketoacidosis

DM	Diabetes Mellitus
DSME	Diabetes Self-management Education
DTSQ	Diabetes Treatment Satisfaction Questionnaire
e-Health	Electronic Health Technologies
EBF	Engagement Behavioural Framework
EC	European Commission
ED	Education
ED_TA	Education Treatment Adherence
ED_UA	Education Usage Adherence
EHC	Effective Health Communication
EHR	Electronic Health Record
ELM	Elaboration Likelihood Model
EMR	Electronic Medical Record
EU	European Union
FP7	Seventh Framework Programme
G-OD	Goal Oriented Design
GDM	Gestational Diabetes Mellitus

GL	Glycaemic Level
GL_TA	Glycaemic Level Treatment Adherence
GL_UA	Glycaemic Level Usage Adherence
GST	Goal-Setting Theory
GUI	Graphical User Interface
HAN	Home Area Network
HbA1c	Glycated haemoglobin
HBM	Health Belief Model
HC	Health Care
HIE	Health Information Exchanges
HIN	Healthcare Intelligence Network
HIV	Human Immunodeficiency Virus
ICT	Information and Communications Technologies
ID	Identification Number
IDF	International Diabetes Federation
IMB	Information Motivation Behavioural
iOS	iPhone OS

IT	Information Technologies
ITDM	Information Technology Diabetes Management
JRE	Java Runtime Environment
KAP	Knowledge, Attitude, Practice
L1	Level 1
L2	Level 2
L3	Level 3
L4	Level 4
LDL	Low Density Lipoprotein
LT	Long Term
M	Mean
Mb	Megabyte
m-Health	Mobile Health Technologies
MCC	Multiple Chronic Conditions
MD	Medication
MD_TA	Medication Treatment Adherence
MD_UA	Medication Usage Adherence

ME	Measurements
MET	Metabolic Energy Equivalent
METABO	Controlling Chronic Diseases related to Metabolic Disorders
MHBC	Multiple Health Behaviour Change
MMR	Measles, mumps, and rubella
MP	Medical Panel
NCPA	National Community Pharmacists Association
NHS	National Health Service
NU	Nutrition
NU_TA	Nutrition Treatment Adherence
NU_UA	Nutrition Usage Adherence
OHA	Oral Hypoglycaemic Agent
OMS	Organización Mundial de la Salud
OS	Operating System
PA	Physical Activity
PA_TA	Physical Activity Treatment Adherence
PA_UA	Physical Activity Usage Adherence

PMD	Patient Monitoring Device
PMT	Protection Motivation Theory
PRS	Professional Subsystem
PRST	Professional Station
PS	Patient Station
PT	Technology Persuasion Principles
PTS	Patient Subsystem
QUM	Quality Use of Medicines
R&D	Research and Development
RDK	Recommended Daily Kilocalories
RPM	Remote Patient Monitoring
RUP	Rational Unified Process
SCT	Social-cognitive theory
SD	Standard Deviation
SDK	Software Development Kit
SDT	Self Determination Theory
SMD	Standardised Mean Difference

SMS	Short Message Service
SPSS	Statistical Package for the Social Sciences
SQL	Structured Query Language
SSL	Secure Socket Layer
ST	Short Term
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TPB	Theory of Planned Behaviour
TPP	Technology Persuasion Principles
TRA	Reasoned action
TTM	Transtheoretical Model
UCD	User-Centered Design
UK	United Kingdom
UP	Unified Process
US	United States
USB	Universal Serial Bus
UTAUT	Unified Theory of Acceptance and Use of Technology

VM	Virtual Machine
WE	Weight
WE_TA	Weight Treatment Adherence
WE-UA	Weight Usage Adherence
WHA	World Health Assembly
WHO	World Health Organisation
WHR	World Health Report
WM	Windows Mobile
WMD	Weighted Mean Difference

*A TECHNOLOGICAL
FRAMEWORK BASED ON
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IMPROVING ADHERENCE OF
DIABETIC PATIENTS*

Abstract

Worldwide there is an exponential growth in the incidence of Chronic Diseases (CDs), such as: hypertension, cardiovascular and respiratory diseases, as well as diabetes mellitus, leading to rising numbers of deaths worldwide (Beaglehole et al. 2008). In particular, the prevalence of diabetes mellitus (DM) is largely increasing among all ages and constitutes a major worldwide health problem. Diabetes was directly responsible for 1,5 million deaths in 2012 and 89 million Disability-adjusted life year (DALYs) (WHO 2014).

One of the key dilemmas often associated to CD management is the **patients' adherence to treatments**, representing a multi-factorial aspect that requires support in terms of: education, self-management, interaction between patients and caregivers, and patients' engagement. Measuring adherence is complex and, even if widely discussed, there are still no "gold" standards ((Giardini et al. 2015), (Costa et al. 2015).

Patient's engagement, through participation, collaboration, negotiation, and sometimes compromise, enhance opportunities for optimal therapy in which patients take responsibility for their part of the adherence equation. Engaging and involving diabetic patients in treatment decisions, along with professional expertise, can help foster a patient-centered approach to diabetes care (Martin et al. 2005).

Patients' motivation and empowerment are perhaps the two most relevant intervening factors that directly affect self-management of diabetes care. It has been demonstrated that these two factors play an essential role in prescription adherence, as well as for the successful encouragement of a healthy life-style and other behavioural changes (Heneghan et al. 2013). A personalised education plan is indispensable in order to provide the patient with the appropriate tools needed for the effective self-management of the disease (El-Gayar et al. 2013).

Effective communication is at the core of providing patient-centred care since it influences behaviours and attitudes towards a health problem (Frampton et al. 2008). In this regard, interactivity, frequency, timing, and tailoring of text messages may promote adherence to a medication regimen. As a consequence, tailoring text messages to patients can constitute a way of making suggestions and information more relevant and effective (Nundy et al. 2013).

In this context, **mobile health technologies (mHealth)** are playing significant roles in improving adherence to prescribed medications (Krishna et al. 2009). The tailoring of diabetes-specific text messages remains an area of opportunity to improve medication adherence and provide motivation to adults with diabetes but further research is needed to fully understand their effectiveness. Personalized text advices have proven to produce a positive impact on patients' empowerment, self-management, and adherence to prescriptions (Gatwood et al. 2014). mHealth can be used for offering self-management support programs to diabetes patients and at the same time surmounting the technical and financial difficulties involved in diabetes treatment (Free et al. 2013).

The main objective of this research work is to demonstrate that a technological framework, based on behavioural change theories, applied to mHealth domain, allows improving adherence treatment in diabetic patients.

The framework, named Engagement Behavioural Feedback Framework (EBF), is built on top of validated behavioural techniques to frame messages, guide the definition of contents and assess outcomes: elements from the Transtheoretical Model (TTM), the Goal-Setting Theory (GST), Effective Health Communication (EHC) guidelines and Principles of Persuasive Technology (PPT) were incorporated. The TTM helps patients to progress to a next behavioural stage, through specific motivated text messages, and allow clinician's identifying the current stage and tailor its strategies individually. Moreover, TTM guidelines are adopted to set customised goals at a level appropriate to the patient's stage of change. The GST was used to build rules to be applied for enhancing educational intervention and weight loss objectives. Finally, the EHC guidelines and the PPT were applied to increase the effectiveness of messages.

The EBF aims to support patients on improving their prescription adherence and persuade them towards a general improvement in diabetes self-management, by means of personalised text messages, named Automatic Feedback Messages (AFM). After a first profile screening, consisting in identifying meaningful patient characteristics based on treatment needs, attitudes and health care behaviours, customised AFMs are selected by the system, approved by the professional, and finally transferred into the patient interface. During the treatment, the user collects the data into a Patient Monitoring Device (PMD) from a set of medical devices and from manual inputs. Inputs consist in medication intake, diet and physical activity, metabolic measurement monitoring and learning tasks. Patient general engagement is checked by estimating the usage of the system and the adherence of treatment and patient goals status in the short and the long term period. The Behavioural Analysis Module, consisting in a set of rules and equations, calculates the

patient's behaviour. After behavioural analysis is accomplished, the AFM library and the dispatch setting are updated by the AFM Manager module. Updates include the number, the type and the frequency of messages. The AFMs are periodically supervised by the professional who also participates to the refinement of the treatment, adapted to the current transtheoretical stage. The AFMs are segmented in different categories and levels and patients can adjust message delivery in accordance with their personal needs.

The EBF was integrated to the METABO system, designed to facilitate diabetic patients in managing their disease in a less intrusive approach. Patient device corresponds in a mobile platform, while a medical panel interface allows professionals to monitoring the treatment evolution. Specific tools allow professional to check patient adherence and to update the AFMs dispatch management. The EBF was tested in a randomised controlled pilot. The main objective was to examine the feasibility and acceptance of the system. Secondary objectives were also the assessment of the effectiveness of system in terms of adherence improvement, glycaemic control, and quality of life. Participants were recruited from four different clinical centres in Europe. The baseline assessment included demographics, diabetes status, profile information, knowledge about diabetes in general, usage of ICT platforms, opinion and experience about electronic devices and adoption of good practices with diabetes.

Acceptance and the effectiveness evaluation criteria were applied to evaluate the performance of the technological framework. The main objective was the assessment of the effectiveness of system in terms of adherence improvement.

Fifty-four patients participated on the trials. Twenty-six patients were assigned in the intervention group and equipped with mobile where the EBF was installed: 14 patients were T1DM and 12 were T2DM. The control group was composed of 25 patients that were treated through a standard care, without the usage of the EBF. Professional's intervention for both intervention and control groups was carried out by 24 care providers, including endocrinologists, nutritionists, and nurses. In order to evaluate the system acceptability and analyse the users' satisfaction, an online multi-language survey, using LimeSurvey, was produced for both patients and professionals. Results were also collected from the log-files generated in the PMDs, the professional medical panel and the entries of the data base. The messages sent to and from the EBF and the log-files of the system and communication services were recorded over 5 weeks of the study. A total of 2795 messages were submitted, representing an average of 107,50 messages per patient. As demonstrated, messages decrease over time indicating an overall improvement of the care plan's adherence.

As expected, T1DM patients were more loaded with short-term advices, in accordance with their condition. Similarly, being the focus of T2DM on long-term sustainable lifestyle changes, T2DM received more reminders advices, as for diet and physical activity.

Favourable outcomes were observed for treatment and usage adherences of the intervention group: for both the adherence indices, results denoted a general improvement on each care plan's dimension, such as on nutrition and blood glucose input measurements. Further studies were conducted on the change on educational level before and after the trial, measured for both control and intervention groups. The outcomes indicated the intervention group has improved its level of knowledge, while the control group denoted a low decrease.

The correlation analysis between the level of adherences and the AFMs showed an improvement in usage adherence for patients who received warnings message, while non-significantly yet even positive indicators related to both treatment and usage adherence correlated with the Reminders. Moreover, the AFMs seemed to help those patients who did not take their treatment seriously enough in the beginning and who were willing to respond to the messages they received. Even though, patients who received too many Warnings, started to consider the message dispatch to be a bit stressful.

The research work carried out in developing this research work provides responses to the four research **hypothesis** that were the motivation for the work:

- **Hypothesis 1**: It is possible to define a set of criteria to measure adherence in diabetic patients.
- **Hypothesis 2**: It is possible to design a technological framework, based on the aforementioned criteria and behavioural change theories, to engage diabetic patients in managing their disease and adhere to care plans.
- **Hypothesis 3**: It is possible to implement the technological framework in the mobile health domain.
- **Hypothesis 4**: It is possible to use the technological framework as a mobile health solution in a real context and have positive effects in terms of diabetes management indicators.

The verification of each hypothesis allowed us to provide a response to the main hypothesis:

The Main Hypothesis is: It is possible to improve diabetic adherence through a mHealth technological framework based on behavioural change theories.

The work carried out to answer these questions is explained in this research work. The framework was developed and applied in the METABO project. METABO is an R&D project, co-funded by the European Commission (METABO 2008) that integrates mobile infrastructure for supporting the monitoring, management, and treatment of type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) patients.

Sinopsis

En todo el mundo se ha observado un crecimiento exponencial en la incidencia de enfermedades crónicas como la hipertensión y enfermedades cardiovasculares y respiratorias, así como la diabetes mellitus, que causa un número de muertes cada vez mayor en todo el mundo (Beaglehole et al., 2008). En concreto, la prevalencia de diabetes mellitus (DM) está aumentando de manera considerable en todas las edades y representa un serio problema de salud mundial. La diabetes fue la responsable directa de 1,5 millones de muertes en 2012 y 89 millones de años de vida ajustados por discapacidad (AVAD) (OMS, 2014).

Uno de los principales dilemas que suelen asociarse a la gestión de EC es la **adherencia de los pacientes a los tratamientos**, que representa un aspecto multifactorial que necesita asistencia en lo relativo a: educación, autogestión, interacción entre los pacientes y cuidadores y compromiso de los pacientes. Medir la adherencia del tratamiento es complicado y, aunque se ha hablado ampliamente de ello, aún no hay soluciones “de oro” (Reviews, 2002).

El compromiso de los pacientes, a través de la participación, colaboración, negociación y a veces del compromiso firme, aumentan las oportunidades para una terapia óptima en la que los pacientes se responsabilizan de su parte en la ecuación de adherencia. Comprometer e involucrar a los pacientes diabéticos en las decisiones de su tratamiento, junto con expertos profesionales, puede ayudar a favorecer un enfoque centrado en el paciente hacia la atención a la diabetes (Martin et al., 2005).

La motivación y atribución de poder de los pacientes son quizás los dos factores interventores más relevantes que afectan directamente a la autogestión de la atención a la diabetes. Se ha demostrado que estos dos factores desempeñan un papel fundamental en la adherencia a la prescripción, así como en el fomento exitoso de un estilo de vida sana y otros cambios de conducta (Heneghan et al., 2013). Un plan de educación personalizada es indispensable para proporcionarle al paciente las herramientas adecuadas que necesita para la autogestión efectiva de la enfermedad (El-Gayar et al. 2013).

La comunicación efectiva es fundamental para proporcionar una atención centrada en el paciente puesto que influye en las conductas y actitudes hacia un problema de salud ((Frampton et al. 2008). En este sentido, la interactividad, la frecuencia, la temporalización y la adaptación de los mensajes de texto pueden promover la adherencia a un régimen de medicación. Como consecuencia, adaptar los mensajes

de texto a los pacientes puede resultar ser una manera de hacer que las sugerencias y la información sean más relevantes y efectivas (Nundy et al. 2013).

En este contexto, **las tecnologías móviles en el ámbito de la salud (mHealth)** están desempeñando un papel importante al conectar con pacientes para mejorar la adherencia a medicamentos recetados (Krishna et al., 2009). La adaptación de los mensajes de texto específicos de diabetes sigue siendo un área de oportunidad para mejorar la adherencia a la medicación y ofrecer motivación a adultos con diabetes. Sin embargo, se necesita más investigación para entender totalmente su eficacia. Los consejos de texto personalizados han demostrado causar un impacto positivo en la atribución de poder a los pacientes, su autogestión y su adherencia a la prescripción (Gatwood et al., 2014). mHealth se puede utilizar para ofrecer programas de asistencia de autogestión a los pacientes con diabetes y, al mismo tiempo, superar las dificultades técnicas y financieras que supone el tratamiento de la diabetes (Free et al., 2013).

El objetivo principal de este trabajo de investigación es demostrar que un marco tecnológico basado en las teorías de cambios de conducta, aplicado al campo de la mHealth, permite una mejora de la adherencia al tratamiento en pacientes diabéticos.

Como método de definición de una solución tecnológica, se han adoptado un conjunto de diferentes técnicas de conducta validadas denominado marco de compromiso de retroacción conductual (EBF, por sus siglas en inglés) para formular los mensajes, guiar el contenido y evaluar los resultados. Los estudios incorporan elementos del modelo transteórico (TTM, por sus siglas en inglés), la teoría de la fijación de objetivos (GST, por sus siglas en inglés) y los principios de comunicación sanitaria persuasiva y eficaz. Como concepto general, el modelo TTM ayuda a los pacientes a progresar a su próxima fase de conducta a través de mensajes de texto motivados específicos y permite que el médico identifique la fase actual y adapte sus estrategias individualmente. Además, se adoptan las directrices del TTM para fijar objetivos personalizados a un nivel apropiado a la fase de cambio del paciente. La GST encierra normas que van a ponerse en práctica para promover la intervención educativa y objetivos de pérdida de peso. Finalmente, los principios de comunicación sanitaria persuasiva y eficaz aplicados a la aparición de los mensajes se han puesto en marcha para aumentar la efectividad.

El EBF tiene como objetivo ayudar a los pacientes a mejorar su adherencia a la prescripción y encaminarlos a una mejora general en la autogestión de la diabetes mediante mensajes de texto personalizados denominados mensajes de retroacción automáticos (AFM, por sus siglas en inglés). Después de una primera revisión del perfil, consistente en identificar características significativas del paciente basadas

en las necesidades de tratamiento, actitudes y conductas de atención sanitaria, el sistema elige los AFM personalizados, los aprueba el médico y al final se transfieren a la interfaz del paciente. Durante el tratamiento, el usuario recopila los datos en dispositivos de monitorización de pacientes (PMD, por sus siglas en inglés) de una serie de dispositivos médicos y registros manuales. Los registros consisten en la toma de medicación, dieta y actividad física y tareas de aprendizaje y control de la medida del metabolismo. El compromiso general del paciente se comprueba al estimar el uso del sistema y la adherencia del tratamiento y el estado de los objetivos del paciente a corto y largo plazo. El módulo de análisis conductual, que consiste en una serie de reglas y ecuaciones, calcula la conducta del paciente. Tras lograr el análisis conductual, el módulo de gestión de AFM actualiza la lista de AFM y la configuración de los envíos. Las actualizaciones incluyen el número, el tipo y la frecuencia de mensajes. Los AFM los revisa periódicamente el médico que también participa en el perfeccionamiento del tratamiento, adaptado a la fase transteórica actual. Los AFM se segmentan en distintas categorías y niveles y los pacientes pueden ajustar la entrega del mensaje de acuerdo con sus necesidades personales.

El EBF se ha puesto en marcha integrado dentro del sistema METABO, diseñado para facilitar al paciente diabético que controle sus condiciones relevantes de una manera menos intrusiva. El dispositivo del paciente se vincula en una plataforma móvil, mientras que una interfaz de panel médico permite que los profesionales controlen la evolución del tratamiento. Herramientas específicas posibilitan que los profesionales comprueben la adherencia del paciente y actualicen la gestión de envíos de AFM. El EBF fue probado en un proyecto piloto controlado de manera aleatoria. El principal objetivo era examinar la viabilidad y aceptación del sistema. Los objetivos secundarios eran también la evaluación de la eficacia del sistema en lo referente a la mejora de la adherencia, el control glucémico y la calidad de vida. Se reclutaron participantes de cuatro centros clínicos distintos en Europa. La evaluación del punto de referencia incluía datos demográficos, estado de la diabetes, información del perfil, conocimiento de la diabetes en general, uso de las plataformas TIC, opinión y experiencia con dispositivos electrónicos y adopción de buenas prácticas con la diabetes.

La aceptación y eficacia de los criterios de evaluación se aplicaron para valorar el funcionamiento del marco tecnológico. El principal objetivo era la valoración de la eficacia del sistema en lo referente a la mejora de la adherencia.

En las pruebas participaron 54 pacientes. 26 fueron asignados al grupo de intervención y equipados con tecnología móvil donde estaba instalado el EBF: 14 pacientes tenían T1DM y 12 tenían T2DM. El grupo de control estaba compuesto por 25 pa-

cientes que fueron tratados con atención estándar, sin el empleo del EBF. La intervención profesional tanto de los grupos de control como de intervención corrió a cargo de 24 cuidadores, entre los que incluían diabetólogos, nutricionistas y enfermeras. Para evaluar la aceptabilidad del sistema y analizar la satisfacción de los usuarios, a través de LimeSurvey, se creó una encuesta multilingüe tanto para los pacientes como para los profesionales. Los resultados también se recopilaron de los archivos de registro generados en los PMD, el panel médico profesional y las entradas de la base de datos. Los mensajes enviados hacia y desde el EBF y los archivos de registro del sistema y los servicios de comunicación se grabaron durante las cinco semanas del estudio. Se entregaron un total de 2795 mensajes, lo que supuso una media de 107,50 mensajes por paciente. Como se muestra, los mensajes disminuyen con el tiempo, indicando una mejora global de la adherencia al plan de tratamiento.

Como se esperaba, los pacientes con T1DM recibieron más consejos a corto plazo, en relación a su estado. Del mismo modo, al ser el centro de T2DM en cambios de estilo de vida sostenible a largo plazo, los pacientes con T2DM recibieron más consejos de recomendación, en cuanto a dietas y actividad física.

También se ha llevado a cabo una comparación de la adherencia e índices de uso para pacientes con T1DM y T2DM, entre la primera y la segunda mitad de la prueba. Se han observado resultados favorables para el uso. En lo relativo a la adherencia, los resultados denotaron una mejora general en cada dimensión del plan de tratamiento, como la nutrición y las mediciones de inserción de glucosa en la sangre. Se han llevado a cabo más estudios acerca del cambio a nivel educativo antes y después de la prueba, medidos tanto para grupos de control como de intervención. Los resultados indicaron que el grupo de intervención había mejorado su nivel de conocimientos mientras que el grupo de control mostró una leve disminución.

El análisis de correlación entre el nivel de adherencia y las AFM ha mostrado una mejora en la adherencia de uso para los pacientes que recibieron los mensajes de tipo alertas, y unos resultados no significativos aunque positivos relacionados con la adherencia tanto al tratamiento que al uso correlacionado con los recordatorios. Por otra parte, los AFM parecían ayudar a los pacientes que no tomaban suficientemente en serio su tratamiento en el principio y que sí estaban dispuestos a responder a los mensajes recibidos. Aun así, los pacientes que recibieron demasiadas advertencias, comenzaron a considerar el envío de mensajes un poco estresante.

El trabajo de investigación llevado a cabo al desarrollar este proyecto ofrece respuestas a las cuatro **hipótesis** de investigación que fueron la motivación para el trabajo.

- **Hipótesis 1:** es posible definir una serie de criterios para medir la adherencia en pacientes diabéticos.
- **Hipótesis 2:** es posible diseñar un marco tecnológico basado en los criterios y teorías de cambio de conducta mencionados con anterioridad para hacer que los pacientes diabéticos se comprometan a controlar su enfermedad y adherirse a planes de atención.
- **Hipótesis 3:** es posible poner en marcha el marco tecnológico en el sector de la salud móvil.
- **Hipótesis 4:** es posible utilizar el marco tecnológico como solución de salud móvil en un contexto real y tener efectos positivos en lo referente a indicadores de control de diabetes.

La verificación de cada hipótesis permite ofrecer respuesta a la hipótesis principal:

La hipótesis principal es: es posible mejorar la adherencia diabética a través de un marco tecnológico mHealth basado en teorías de cambio de conducta.

El trabajo llevado a cabo para responder estas preguntas se explica en este trabajo de investigación. El marco fue desarrollado y puesto en práctica en el Proyecto METABO. METABO es un Proyecto I+D, cofinanciado por la Comisión Europea (METABO 2008) que integra infraestructura móvil para ayudar al control, gestión y tratamiento de los pacientes con diabetes mellitus de tipo 1 (T1DM) y los que padecen diabetes mellitus de tipo 2 (T2DM).

Chapter 1

Introduction

1.1 The problem

Worldwide there is an exponential growth in the incidence of Chronic Diseases (CDs), such as: hypertension, cardiovascular and respiratory diseases, as well as diabetes mellitus, leading to rising numbers of deaths worldwide (Beaglehole et al. 2008). In particular, the prevalence of diabetes mellitus (DM) is largely increasing among all ages and constitutes a major worldwide health problem. Diabetes was directly responsible for 1,5 million deaths in 2012 and 89 million Disability-adjusted life year (DALYs) (WHO 2014).

One of the key dilemmas often associated to CD management is the patients' adherence to treatments, representing a multi-factorial aspect that requires support in terms of: education, self-management, interaction between patients and caregivers, and patients' engagement. Measuring the treatment adherence is complex and, even if widely discussed, there are still no "gold" solutions (Reviews 2002). Patient's engagement, through participation, collaboration, negotiation, and sometimes compromise, enhance opportunities for optimal therapy in which patients take responsibility for their part of the adherence equation. Engaging and involving diabetic patients in treatment decisions, along with professional expertise, can help foster a patient-centered approach to diabetes care (Martin et al. 2005).

The patients engagement includes having a crucial role in their own treatment, having to take , relevant decisions on a daily basis about the actions needed for the management of their disease, such as: dietary choices, glucose monitoring, medication intake, and maintaining a healthy life-style through physical exercises. Patients' motivation and empowerment are perhaps the two most relevant intervening factors that directly affect self-management of diabetes care. It has been demonstrated that these two factors play an essential role in prescription adherence, as well as for the successful encouragement of a healthy life-style and other behavioural changes (Heneghan et al. 2013). A personalised education plan is indispensable in order to provide the patient with the appropriate tools needed for the effective self-management of the disease (El-Gayar et al. 2013).

In this context, mobile health technologies (m-Health) are playing significant roles in connecting with patients to improve adherence to prescribed medications (Krishna et al. 2009). This technology can, in fact, be used for offering self-management support programs to diabetes patients through automatic messages and at the same time surmounting the technical and financial difficulties involved in diabetes treatment (Free et al. 2013).

Effective communication is at the core of providing patient-centred care since it influences behaviours and attitudes towards a health problem (Frampton et al.

2008). In this regard, interactivity, frequency, timing, and tailoring of text messages may promote adherence to a medication regimen. As a consequence, tailoring text messages to patients can constitute a way of making suggestions and information more relevant and effective (Nundy et al. 2013).

There are presently many adherence apps available on the market for Android and Apple iPhone OS (Dayer et al. 2013). Even so, such solutions do not foresee a constant clinical follow-up and frequently lack in horizontal methods like educational guidelines and customized automatic control. Moreover, it has not been proven yet that apps can actually modify patients' adherence and what patients could be benefited the most.

Even if the efficacy of the use of automatic messages in DM has been preliminarily demonstrated in several studies (Free et al. 2013), several barriers to self-management still exist and studies are needed to determine the real impact of education and support systems in patients' behavioural plasticity and actual treatment compliance (Tang et al. 2012).

Presently, some of the most relevant limitations are:

Lack of customisation: There are no innovative provisions for follow-up, designed in a way that meets the needs of a particular patient group while also conforming to clinical guidelines.

Lack of dynamicity of text messages: Especially related to patients' behaviour, risk factors, medical condition, life-style, environment, or patients' emotional state.

Lack of real-time intervention from clinicians: If a patient has a medical issue that could adversely affect their condition, there is a lack of a real-time intervention tool that would allow an instantaneous reaction from the clinician for treatment.

The tailoring of diabetes-specific text messages remains an area of opportunity to improve medication adherence and provide motivation to adults with diabetes, however further research is needed to fully understand their effectiveness. Personalised text advices have proven to produce a positive impact on patients' empowerment, self-management, and adherence to prescriptions (Gatwood et al. 2014).

1.2 Hypothesis and Objectives

Basing on these premises, the following **hypotheses** have been drafted:

- **Hypothesis 1**: It is possible to define a set of criteria to measure adherence in diabetic patients.
- **Hypothesis 2**: It is possible to design a technological framework, based on the aforementioned criteria and behavioural change theories, to engage diabetic patients in managing their disease and adhere to care plans.
- **Hypothesis 3**: It is possible to implement the technological framework in the mobile health domain.
- **Hypothesis 4**: It is possible to use the technological framework as a mobile health solution in a real context and have positive effects in terms of diabetes management indicators.

The **Main Hypothesis** is: It is possible to improve diabetic adherence through a mHealth technological framework based on behavioural change theories.

The **Objectives** are:

- **Objective 1**: Define a set of mathematical equations and conditions for estimating the adherence in diabetic treatment.
- **Objective 2**: Define a technological framework, based on automatic text messaging, tailored specifically to diabetic patients for improving their prescription adherence.
- **Objective 3**: Implementation of the technological framework in the mHealth domain.
- **Objective 4**: Assessing the positive effects of the technological framework in diabetes adherence, compared with the standard care.

The **Main Objective** is: development of a technological framework, based on behavioural change theories applied to a mHealth domain that allows the improvement of adherence treatment in diabetic patients.

The work carried out to answer these questions is explained in this research work. The framework was developed and applied in the METABO project. METABO is an R&D project, co-funded by the European Commission (METABO 2008) that integrates mobile infrastructure for supporting the monitoring, management, and

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treatment of type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) patients.

1.3 Motivation and structure of the research work

The motivation of this research work arises from the need of improving the quality of life of individuals suffering from a chronic disease. Since the beginning, diabetes disease was selected as a main objective for the purpose of the work, being one of the ten deadliest diseases, but, at the same time, partially preventable. The possibility to work for seven years on the diabetes quality of the care, with the support of clinical professionals and biomedical engineers, has been motivating the research work carried out and reported here. In particular, the opportunity to contribute on improving the quality of the care plan management, through the implementation of psychological technique in the mobile health domain, was a high stimulus for the research work carried out and reported on this document.

The technological framework proposed in this research work is a structured contribution to achieve these improvements.

The structure of the document is as follows:

Chapter 1 has introduced the problem of the burden of diabetes treatment and the need to identify effective methods to improve its adherence.

Chapter 2 provides the socio-economic and technological background around which the research work has been developed.

Chapter 3 explores the adherence in diabetes treatment and the more suitable behavioural change theories applied, with special emphasis on solutions based on mobile health.

Chapter 4 sets the methodological basis for the development of this work.

Chapter 5 describes the technological framework and its implementation within the METABO project.

Chapter 6 provides the evidence collected to justify the quality of this work.

Chapter 7 draws the conclusions of the work and some possible future extensions.

Chapter 2

Literature Review

This chapter introduces the burden of chronic diseases, focusing on diabetes mellitus. The identification of the main issues derived from suffering of diabetes are presented, as the latest estimates on the number, rates and causes of global deaths from diabetes and the prevalence of the most important related risk factors. Furthermore, the current barriers and challenges on diabetes treatment are illustrated for type 1 and type 2 diabetic patients, stressing on the importance of following an appropriate and customised care plane. Finally, an overall vision of the ICT current solutions and investments for helping diabetic patients in managing their disease and adhering to care plans are presented.

2.1 Chronic diseases

Chronic diseases (CDs) are known to persist over long periods and cause disruption of life in many ways. Although some CDs can be controlled or managed through certain medications and lifestyle (diet and exercise), they last for a very long time and usually cannot be cured completely. Some common examples of chronic illnesses are: diabetes, heart disease, arthritis, kidney disease, HIV/AIDS, lupus, and multiple sclerosis (Simon 2001).

In general, CDs usually emerge in middle age and their presence is strongly related to a prolonged exposure of an unhealthy lifestyle, such as: tobacco use, a lack of regular physical activity, and consumption of diets rich in highly saturated fats, sugars, and salt (Steyn, K., & Damasceno 2006). These conditions can increase risk factors, such as hypertension, dyslipidaemia, diabetes, and obesity, all of which can act independently and synergistically (Steyn, K., & Damasceno 2006). According to the World Health Report (WHR), (WHO 2014), CDs are the leading cause of death and disability worldwide. Disease rates are advancing globally across every region and invading all socio-economic classes. The mortality, morbidity and disability caused by major CDs currently accounts for 60% of all deaths and 46% of the global burden of disease (Harris 2013). The proportion of the burden of CDs is expected to increase to 57% by 2020. A significant number of CD deaths are attributed to cardiovascular diseases; however, research data shows that obesity and diabetes also have worrying trends.

As the leading cause of death globally, CDs were responsible for 38 million (68%) of the world's 56 million deaths in 2012. More than 40% of them (16 million) were premature deaths under the age of 70 years. Almost three quarters of all CD deaths (28 million), and the majority of premature deaths (82%), occur in low- and middle-income countries (WHO 2014).

According to (Compas et al. 2012), having a long term, or chronic illness affects the appearance, physical abilities and independence of the affected individuals. This is even more problematic and frightening for children because they may not understand why this is happening to them. These changes can cause anger, anxiety and stress. It is evident that the child who is diagnosed with a serious and chronic medical illness is at greater risk for developing emotional problems. This happens because the child with a chronic illness must cope with knowing that their problem is incurable, is permanent and may even get worse with time. Moreover, chronic illness entails frequent physician visits and medical leaves which mean that the child or adolescent will miss school and other daily activities. When this happens frequently, it may cause problems, including refusal to attend school and increasing the child's loneliness and feeling of being different from other children. Research indicates that at particular risk of psychological distress are people who are experiencing a number of stressful life events before diagnosis, and those with a history of depression. However, it was shown that even people with relatively few stresses in life can have strong negative feelings by a CD diagnosis. It is common to experience various stages of grief including denial, bargaining, anger and sadness (Frank 2002). It is important to mention that often individuals suffer from multiple chronic conditions and the health consequences of such situations are still poorly understood. Some studies suggest that specific diseases may be associated with disability only when another specific disease is present. In such cases, individuals must take more medications at the same time, which means that they can suffer from adverse drug interactions and as a consequence cannot participate effectively in their own care (Vogeli et al. 2007).

Evidence has shown that in the last years, people with chronic illness are reported to be in better health than people 20 years ago. This is mainly due to early diagnosis, where 60% of cases of people treated for five or more conditions are reported to be in good or excellent health conditions in 2002, while only 33% of cases are reported to have similar health status in 1987 (Thorpe & Howard 2006).

It is expected that the prevalence rate of many conditions which are characteristic for the aged, will increase by more than 25% over a quarter century. Recent outcomes show that health care resource use increases strongly with age and number of chronic conditions and, if the number of conditions were to be maintained, the health care requirements would grow more rapidly than the population - more than twice as rapidly in the case of hospital stays for example (Frank T. Denton & Byron G. Spencer 2015). However, the positive news is that some research data concluded that not all chronic illnesses are on the rise. The prevalence of some chronic conditions has remained relatively stable or have even decreased over the past decade.

Examples of less prevalent conditions are congestive heart failure, dementia, hip fracture, and kidney diseases (AARP Public Policy Institute 2014).

The general opinion is that the highest quality of care provided to individuals that suffer from such diseases will not guarantee the improvement of health outcomes. There is a great need to design strategies that help individuals regain a sense of control over their life and improve quality of life. Among others, four interdependent goals can help achieve health and quality of life for individuals with multiple chronic conditions. (1) foster health-care and public health system changes to improve the health of individuals with Multiple Chronic Conditions (MCC); (2) maximise the use of proven self-care management (3) provide better tools and information to health-care and public health systems (4) facilitate research to fill knowledge gaps about, and interventions and systems to benefit, individuals with MCC (Vogeli et al. 2007). Scientists argue also that taking actions at the beginning of diseases will help individuals to understand and deal with the many effects of a chronic illness. Indeed, stress management will enable patients to maintain a positive physical, emotional and spiritual outlook on life (Compas et al. 2012). An important lesson is that it is possible to prolong the life of people with CDs by several decades, thereby avoiding deaths among middle-aged people. In other words, successful interventions early in life have the potential to reduce substantially the CD pandemic. No doubt that new patient focused technologies will contribute more efficiently and effectively to support older individuals and improve CD management (Dexter et al. 2010).

2.2 Population ageing

Ageing is described by many authors as a dynamic process, determined by the relative size of the younger and older cohorts in the population at different moments in time. Recently, the world population is experiencing significant ageing and increasing proportions of older people. It is evident that ageing is taking place almost everywhere. Even if in more developed regions this process has started earlier, however it is also present in some developing countries and is becoming more evident at the global scale (Affairs. 2013).

According to the “Analysing structural reforms and EU policies”, the population in Europe will be slightly higher in 2060 (517 million, up from 502 million in 2010) and much older. The increase of the ageing of the population will pose significant challenges for the economies and the welfare systems of European countries. Notably, the share of those aged 15-64 is projected to decline from 67% to 56% by 2060. The share of those aged 65 and over is projected to rise from 17% to 30% (European Commission 2012).

Ageing has profound consequences on a broad range of economic, political and social processes. Over the next few decades for some countries the trend of demographic transitions will define their economic landscape. For example, social support systems, which are vital for the well-being of both the older and younger generations might experience serious challenges in the future. While people live longer, retirement, pensions and other social benefits tend to extend over longer periods of time. This means that social security systems should make substantial changes and adjustments in order to remain effective. While the technology is evolving and economies are globalising there are more chances that a large number of people will be living in cities. The demographic data shows that people today have fewer children, and they more likely to prefer to live separated from older generations (Services 2011). This reality means less support from families, which is an indication that society needs better information tools to ensure the well-being of the world's growing number of older citizens. Another concern is rising medical costs and increasing demands for health services, since older people are typically more vulnerable to CDs. Indeed, chronic and degenerative diseases are more common and are one of the characteristics of the older population, which results in the increased prevalence of CDs at the population level. As a population ages, the demands for health care systems are increasing, which also increases the medical costs, because older people usually require more health care in general and more specialised services to deal with their complex pathologies. The number of deaths also increases sharply due to the exponential increase in mortality with age. It has been shown that as the population gets older, the number of CDs such as heart disease, cancer and diabetes, increases significantly (Affairs. 2013). Moreover, other factors such as: the increasing levels of tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol in developing regions could have long-term consequences as these risk factors can have cumulative effects over the life-cycle (Haveman-Nies et al. 2003). Recent evidence shows that various health problems are associated with the aged population and they affect a wide and expanding swathe of the world population. It is expected that in the coming 10 to 15 years in every world region, people will suffer and experience more disabilities and death from such CDs than from infectious and parasitic diseases (Un Population Division 2012). Figure 1 shows the incidence of a number of pathologies with the age. These include diabetes, heart disease, cancer, arthritis, and kidney disease.

Figure 1. Prevalence of selected chronic conditions, expressed in percentages, as a function of age for the US population (2002-2003 dataset). All forms of cancer and heart disease are featured (Statistics 2005).

One important reason why more people are developing chronic illness is improved health care for many acute illnesses and diseases. These recent advances help to keep people alive longer, thereby increasing the chance for them to develop a CD while allowing them to live longer. According to the World Health Organisation (WHO), many countries have developed a slow response to new disease patterns and aging populations. Based on the existing facts, there is a great need for new policies for all age segments of the population, especially with an aging population in mind, considering that soon every third individual will be over the age of 60. At the same time all communities must start to adjust and design their infrastructure, policies, plans and resources to accommodate the expanding ageing population (Services 2011).

2.3 Diabetes

Diabetes is a CD that occurs either when beta cells in pancreas do not produce insulin, produce too little or when the body cannot effectively use the insulin it produces (Thrower 2015). The first clear written description of diabetes was produced by Aretaeus of Cappadocia in the first century AD, who recognised its symptoms and commented that "life (with diabetes) is short, disgusting and painful." (Francis 1856). T1DM and T2DM were identified as separate conditions for the first time by the Indian physicians Sushruta and Charaka in 400-500 CE with T1DM associated with youth and T2DM with being overweight (Poretsky 2010).

Today we can distinguish diabetes in three main categories: Diabetes Mellitus Type 1 (T1DM), Diabetes Mellitus Type 2 (T2DM), and Gestational Diabetes Mellitus (GDM). T1DM is characterised by deficient insulin production, and constant need for treatment in the form of insulin injections or an insulin pump. This condition

accounts for approximately 5–10% of all cases of diabetes, however, its incidence continues to increase worldwide. T2DM occurs when the pancreas does not produce enough insulin or the body is not able to use it effectively. The majority of patients with diabetes have T2DM. GDM is characterised by blood glucose values above the normal, but below the diagnostic range for diabetes and usually women acquire this type of diabetes during their second trimester of pregnancy (D. O. F. Diabetes 2009).

As the population is growing and aging, the prevalence of obesity and lack of physical activity is also increasing, this results in a direct rise in the number of people being diagnosed with diabetes. Research data shows that the prevalence of diabetes for all age-groups worldwide was expected to be 2,8% in 2000 and 4,4% in 2030. The total number of people with diabetes is also expected to increase from 171 million in 2000 to 366 million in 2030. Although, the prevalence of diabetes is higher in men than women, research findings indicate that there are still more women with diabetes than men (Sarah, W., Gojka, R., Anders, G., Richard, S., & Hilary 2004). According to the International Diabetes Federation (IDF) report, the number of people living with diabetes is estimated to increase to 55% by 2035, where the highest percentages will be in Africa (109%), the Middle East and North Africa (96%), and South-East Asia (71%).

Figure 2 shows the current and projected diabetes cases by region as well as the top 10 countries by number of people with diabetes in 2013, ages 20-79.

World diabetes cases expected to jump 55 percent by 2035

Figure 2. Current and projected diabetes cases by region as well as top 10 countries by number of people with diabetes in 2013, ages 20-79 (Aguirre F, Brown A, Cho NH, Dahlquist G, Dodd S, Dunning T, Hirst M, Hwang C, Magliano D, Patterson C, Scott C, Shaw J, Soltesz G, Usher-Smith J 2013).

A study in which age-specific data were examined, on estimation for prevalence of DM showed that diabetes rose with age in all populations (Hilary King & Marian Rewers 1993).

In the European region the prevalence of diabetes continues to increase, resulting in more disabilities and enormous health care costs. Due to the large diversity within the EU countries, the prevalence of diabetes in Europe ranges from 2,4% in Moldova to 14,9% in Turkey. The screening programmes show that a significant number of people (up to 50%) with diabetes are undiagnosed. Together with other health consequences, diabetes mellitus has a high cost and negative health implications, while several EU governments lack a clear view of the disease's epidemiological burden, economic, personal, and societal impact. It is estimated that total cost of diabetes across the EU is from 2,5% – 15% of total healthcare spending (Hall, M., Felton, A. M., Tuomilehto, J., & Hughes 2008).

In most European countries the incidence of T1DM is increasing in young people as well as the prevalence in all age groups. T2DM, as a major contributor to the epidemic rise, was increased also considerably in the UK, Germany and France (Passa 2002). The differences of distribution of risk factors for diabetes in the EU are a

major challenge for health service in the European countries (Tamayo et al. 2014). This difference in prevalence and costs are attributed to the differences between countries in terms of technology, lifestyle, healthcare systems, treatment and management. The most common factors that are influencing the increase of diabetes prevalence among all ages in the European region are being overweight and obesity, unhealthy diet and poor physical activity.

Studies have revealed that another important factor to be considered is the socio-economic disadvantages which contribute in the development of diabetes through inequitable access to quality treatment and environmental conditions that promote unhealthy choices (European Commission 2007). Research data that measures the inequality in spending on health services shows that wealthier groups have higher probability to obtain care when they have health problems, more likely to be seen by a doctor, and have a better chance to obtain medicines when they are ill compared to poorer groups (Makinen et al. 2000). Various factors can contribute to the proper access of diabetes healthcare, such as the level of education of those who need care, the distance needed for patients to travel and get the necessary service, the geographical distribution of the health services and the health care payment process. Results have shown, for example, that the incidence of diabetes is more prevalent in low-education groups, and people with lower levels of education are less likely to be diagnosed and to adhere to treatment. In some countries the health care for diabetes is very limited due to the concentration of health services in urban cities. It was also concluded that people without health insurance, especially in countries without universal access to health care systems, have less examinations and very poor outcomes (Aagaard-Hansen & Chaignat 2010). Figure 3, shows an overview of the social and environmental determinants of T2DM.

Figure 3. Multifactorial models showing the social and environmental determinants of T2DM (Hee 2010).

Several studies have revealed how societal factors are driving the diabetes epidemic in all countries. For example, poor people have a higher risk to be exposed to an obesogenic environment and have worse health outcomes. Moreover, poor women are more vulnerable to poor nutrition during pregnancy which in turn can increase the chances for children to be exposed to the risk factors for diabetes (Aagaard-Hansen & Chaignat 2010).

Diabetes can cause a number of complications and health problems. Abnormal glucose levels can result in serious diseases that affect the heart, eyes, kidneys, nerves, teeth and diabetic foot pathologies. In case of pregnancy for instance, in order to avoid and prevent diabetic complications, women with diabetes require regular monitoring for these diseases and related complications during pregnancy (Aguiree F, Brown A, Cho NH, Dahlquist G, Dodd S, Dunning T, Hirst M, Hwang C, Magliano D, Patterson C, Scott C, Shaw J, Soltesz G, Usher-Smith J 2013).

From a biochemical point of view, some acute metabolic complications associated with mortality include diabetic ketoacidosis from exceptionally high blood glucose concentrations (hyperglycaemia) and coma as a result of low blood glucose (hypoglycaemia). The wide range of complications appears to be due to a chronic increase of blood glucose levels which can damage the blood vessels over time. Based on these facts the resulting complications are grouped under “microvascular disease” (due to damage to small blood vessels) and “macrovascular disease” (due to damage to the arteries). Each one of these is associated with other specific symptoms, for example microvascular complications include retinopathy, nephropathy, and neural damage or “neuropathy”. On the other hand, macrovascular complications include accelerated cardiovascular disease resulting in myocardial infarction and cerebrovascular disease manifesting as strokes. Figure 4 shows an overview of the major areas contributing to diabetic complications.

Figure 4. Overview of the major areas that increase and contribute to diabetic complications (Forbes & Cooper 2013).

Older people in particular are at risk of diabetic complications due to the administration of multiple medicines, resulting in higher hospital admissions in people over 80 years of age.

Thus, it is essential to adopt a Quality Use of Medicines (QUM) approach to managing medicines in each older person. The treatment recommendations emphasise that blood pressure and lipid reduction have specific benefits in older people above the age of 70 years, therefore, their control is highly recommended. Indeed, the treatment recommendations are often based on multidimensional and multidisciplinary assessments which collect information on medical, psycho-social and functional capabilities and how these may limit activities (International Diabetes Federation 2013).

In order to prevent diabetes related complications, early diagnosis is very efficient. For this purpose, several testing techniques and methods are in use. The glucose levels in blood are measured using different blood testing assays. The first and most frequently used is a fasting blood glucose test, which measures the blood glucose levels after the person has not eaten for several hours. The second method, which is known as the random blood glucose test, measures the glucose levels in the blood regardless of what the patient ate, or when. The diagnosis is confirmed if the blood

glucose levels are greater than 11 mmol/L for a random blood glucose test. For more detailed confirmation of diagnosis, a glucose tolerance test is also often recommended. This sensitive test is performed using several blood samples while the person drinks a measured quantity of glucose. Monitoring the levels of glucose in blood enables the clinician to identify the severity of the diabetes. Besides diagnosis the testing is used to measure the effectiveness of the treatment. In such cases the Glycated haemoglobin (HbA1c) test is used, which shows the average blood glucose levels over a period of time. However, when diabetes is suspected, doctors may also check other organs and related symptoms, such as: eyes, kidney, and heart (Allen, C. M. C., & Lueck 1999).

2.4 Diabetes management, barriers and challenges

It is well recognised that to prevent complications and ensure good and efficient control of diabetes, it is essential to improve the glycaemic control as the main factor in diabetic complications. Intensifying and improving the existing and future therapies, as well as maintaining near-normal blood glucose levels, can result in a considerable reduction in the risk of development of diseases of the eye, kidney, foot and nerves. Besides monitoring glycaemic control the management strategies are based on dietary therapy, increased physical activity, and drug treatment (Care & Practice 1994).

Medications are necessary to regulate and achieve the desired blood sugar levels. For some individuals a single medication is effective enough, while in other cases a combination of different medications works better. Technology has produced different types and classes of drugs where each one works in different way to lower blood sugar. The most common effects of all drugs are (Mayo Clinic Staff 2014):

- Stimulating the pancreas to produce and release more insulin
- Inhibiting the production and release of glucose from the liver
- Blocking the action of stomach enzymes that break down carbohydrates
- Improving the sensitivity of cells to insulin
- Inhibiting the reabsorption of glucose in the kidneys
- Slowing the speed at which food moves through the stomach

In diabetes management an integral role belongs to nutrition therapy. This type of therapy is recommended for all people with T1DM and T2DM as an effective component of the overall treatment plan.

It is recommended in several studies that each person with diabetes should be actively engaged in self-management, education and treatment planning with health care providers and develops the collaborative and individualised eating plan. Careful selection of food types can have a direct effect on energy balance, body weight, lipid levels and blood pressure. For example, in T2DM the carbohydrate counting meal planning approach can result in improved glycaemic control.

A simple diabetes meal planning approach, such as portion control or healthier food choices may be better suited to individuals with T2DM identified with health and numeracy literacy concerns. However, it is important to mention that there is not any ideal percentage of calories from carbohydrates, protein, or fat that is optimal and efficient for all people with diabetes. Such therapies are usually recommended to be developed in collaboration with individuals with diabetes and based on an assessment of the individual's current eating patterns, preferences, and metabolic goals (Evert et al. 2013). Dietary control can achieve weight reduction which improves the glycaemic control and other cardiovascular risk factors. Evidence shows that even small changes in weight loss (5–10%) have a meaningful contribution to achieving improved glucose control. The types of foods highly recommended are vegetables, fruits, whole grains and legumes, low-fat dairy products, and fresh fish are also emphasised (Inzucchi et al. 2012). Weight loss is an important therapeutic objective due to the effects of obesity on insulin. However, it is difficult to achieve long term weight loss due to control mechanisms based on the central nervous system that regulate energy intake and expenditure.

Standard weight loss diets provide 500–1,000 fewer calories than estimated to be necessary for weight maintenance and initially result in a loss of $\sim 0,45\text{--}0,90$ Kg/week. Results suggest that very-low-calorie diets provide ≤ 800 calories daily and can intensify weight loss substantially as well as improvements in glycaemia and lipemia in individuals with T2DM. However, it is very common that the weight will be compensated when such diets are stopped and self-selected meals are again re-introduced (American Diabetes Association 2008).

Research data support the findings that physical activity may be a therapeutic tool in a variety of patients with the risk of diabetes. It is known that during physical activity, whole-body oxygen consumption may increase by as much as 20-fold and even higher levels are expected in the working muscles. In order to meet this energy level, skeletal muscles use their own stores of glycogen and triglycerides, as well as free fatty acids coming from the liver. While the evidence shows that the epidemic of T2DM is strongly associated with decreasing levels of activity and an increasing prevalence of obesity, it is recommended for patients to accumulate 30 min of moderate physical activity on most days of the week.

The effect of physical activity is better when it is used early in the progression of diabetes from insulin resistance, to impaired glucose tolerance, to overt hyperglycaemia, requiring treatment with oral glucose-lowering agents and finally to insulin (Riddell & Sigal 2013). However, the amount and intensity of exercise recommended depends on the individuals, and goals. Some results recommend at least 150 min/week of moderate-intensity aerobic physical activity and/or at least 90 min/week of vigorous aerobic exercise. For people with T2DM who do not experience contra-indications, it is recommended to perform resistance exercise three times a week. It is also recommended, particularly for those who take insulin, to check capillary blood glucose levels before and after physical activities in order to manage the glycaemic responses to such activity (Kitabchi et al. 2006).

Recent data concluded that the benefits of exercise in T2DM goes beyond glycaemic control and blood pressure reduction. It was shown that exercise can improve the endothelial vasodilator function and left ventricular diastolic function. The changes that occur in body composition can mediate improvements in insulin sensitivity and blood pressure and may improve as a result the endothelial vasodilator function (Stewart 2004). Figure 5 shows some important components that contribute to diabetes management.

Greatest Challenge of Diabetes Management in a Population

Figure 5. Strategies and tactics for the management of diabetes (Network 2012).

There are multiple challenges and barriers in treating and managing the health of people with diabetes. For example, a diagnosis of T2DM can represent a significant challenge for individuals. For many patients a new reality means multiple medications, needle sticks, food restrictions, and multiple visits to health care providers. Since patients have to re-orient their life in a new reality, it is important to have information about social, psychological, environmental, or cognitive barriers that might interfere with a patient's management of their disease or ability to follow the

recommended treatment regimen. Some treatment barriers that patients with T2DM face are (Pharmaceuticals 2014):

- Communication barriers
- Personal barriers
- Self-management barriers
- Care barriers

Other influential factors include the patients' adherence, attitude, beliefs, and knowledge about diabetes. Language capabilities and culture are also known to influence the patient's health beliefs, attitudes, health literacy which finally affects the diabetes self-management. Other influencing factors to consider are the patient's financial resources, co-morbidities, and social support (Nam et al. 2011). One of the most difficult barriers to consider in patients with diabetes is depression. Unfortunately, the relationship between depression and diabetes is bi-directional.

This feature increases the risk of people who are depressed for developing diabetes, and at the same time patients with diabetes have a higher risk of depression. Studies have confirmed that depression is closely associated with worse diabetic outcomes, such as increased complications, poor quality of life, and mortality (Gonzalez et al. 2008). Many research findings support the conclusion that diabetes doubles the odds of depression. Although, the prevalence depends on many factors such as: sex, study design, subject source and assessment methods, the general opinion of clinicians and epidemiologists is that people with diabetes are twice as likely to be depressed than other similar non-diabetic individuals in similar settings (Anderson et al. 2001). It has been noted that interpersonal communication is also influential and can dramatically affect the acceptability of health programmes. Indeed, the most important barrier considered here is language. It was concluded that communication in the language of the client is crucial for effective care. This barrier can raise issues like selecting a direct versus an indirect approach and a confrontational versus a collaborative style (Tripp-Reimer 2001). Personal barriers are emphasised in many papers as important factor in diabetes care. In order to increase the quality of life, community participation and reduce mortality rates, "it is crucial to see through the eyes of those with diabetes". Figure 6 shows some of the personal barriers associated with diabetes care (Simmons 2001).

Figure 6. Personal barriers to diabetes care (Simmons 2001).

Diabetes mellitus is primarily a self-managed condition; therefore, individuals must take various actions in order to manage it successfully. However, the required behaviours are very often difficult for individuals with diabetes to maintain over time. Table 3.1 shows a brief summary of findings of three studies regarding the rank order of barriers by population surveyed.

Table 3.1. Five barriers across populations surveyed

Rank order	Referring Providers' barriers	Diabetes educators at Diabetes Self-Management Education/Ambulatory Diabetes Education and Follow-up Program sites' barriers	Program members with diabetes barriers	Anthem Members with diabetes barriers
1	Transportation issues	Participants feel they do not need it	Aversion to group	Can manage on own
2	Cost issues	Cost issues	Not interested	Program at inconvenient times/dates
3	Aversion to group	Conflicts with scheduling	Participants feel they do not need it	Participants feel they do not need it
4	Program at inconvenient times/dates	Transportation issues	Don't know about DSME program	Time/too busy
5	Too long of wait to begin the program	Time/too busy	Transportation issues	Aversion to group

The table shows that there is not a single reason that stands as a barrier. The classification is based on the theme of lack of need/interest such as: participants feeling they do not need it and can manage on their own, or are not interested. Even though the cost was considered by providers and diabetes educators as the second highest rate barrier, for the individuals with diabetes this was not perceived as one of the top five barriers. According to the table, transportation was mentioned and ranked number one for the referring health care providers as a barrier while, this parameter was ranked as the fourth barrier by diabetes educators (Services 2006). Studies have confirmed that rural residents might not receive the same number

and type of chronic care services compared with their urban counterparts. These barriers can be very problematic for diabetic patients because their health conditions depend on good glycaemic control and early detection.

Patients must also have access to quality medical care in order to prevent diabetes complications. This means that they must pay for services, get the necessary knowledge and skills to manage their diabetes problems on a day-to-day basis. The research work shows that access and self-care are critical contributors to outcomes in patients with diabetes. Therefore, socio-economic mediators (education and/or income) have a significant contribution in these processes. Finally, there are many challenges to understanding barriers in diabetes care. These financial, educational, and access barriers are some examples that demonstrate the need for innovative efforts on the part of health systems and providers to offer increased access to diabetes services in rural settings. There is a great need to understand diabetes barriers from a patient's perspective so that health systems can develop programmes to address and overcome these barriers. Moreover, this process also requires co-operation with those outside the traditional health boundaries: in welfare, in the community, and in the workplace (Zgibor & Songer 2001).

2.5 Adherence in diabetes

According to (Sabaté 2003) adherence can be defined as “the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with the agreed recommendations from a health care provider”. It is not useful to think of adherence as a unitary construct, but rather one which is multidimensional, because patients may adhere well to one aspect of the regimen but not to others (Delamater 2006).

Treatment adherence problems are common in individuals with diabetes, which can make proper management of the condition (primarily achieved through glycaemic control) difficult to attain. This issue has a significant impact on outcomes, despite the widespread availability of educational materials, glucose monitoring tools and medications for managing the disease. In fact, the American Diabetes Association acknowledges that among those with chronic conditions such as diabetes, nearly 50 percent do not consistently follow provider recommended treatment regimens and lifestyle changes (Rinker 2014).

Most research work has been focused on adherence to medication. However, this problem includes numerous health-related behaviours that extends beyond taking prescribed pharmaceuticals. Recent discussions and recommendations have adopted the definition of adherence as the extent to which a person's behaviour

taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider. An important factor for efficient and effective planning is also the correct assessment behaviour which ensures that changes in health outcomes can be attributed to the recommended regimen. Indeed, all decisions to change recommendations, communication style, medications etc., which are essential to promote patient participation depend on valid and accurate measurement of the adherence construct (Sabaté 2003).

Some of the most common methods in use for measure of adherence are: health status indicators, provider ratings, behavioural observations, permanent products, and patient self-report, including behaviour ratings, diaries, and 24-h recall interviews. The selection of the right measurement method should be based on reliability, validity, non-reactivity, and measurement independence from the patient's health status. The timing measurement is also important and the current methods are usually based on the stability of adherence behaviours and temporal congruity with other measures of interest (Johnson 1992).

Despite the importance of the right definition of adherence, different measurements available for adherence make it challenging to compare results. In some cases, adherence is measured based on pill counts that measure the total amount of medication taken, while other research methods consider the timing for taking prescribed medicine. The existing evidence suggests however, that it is necessary to develop a robust and consistent measure of the size of the non-adherence problem globally.

Rates of refilling prescriptions are also accurate methods to measure drugs' adherence in a closed pharmacy system, since refills are measured at several points in that time. Another solution that may help in measuring the adherence includes electronic monitors capable of recording the time of opening medical bottles. The disadvantage with this method is that the level of adherence is not accurate as the patient may open the bottle without taking the medication or take the wrong amount of medication (Jimmy & Jose 2011).

Failing to adhere to medical treatment programmes has consequences for economy of the treatment as well as for patients. The economic impact is more evident in hospitalisation and treatment costs. For patients, these impacts include reduced longevity and quality of life. Recent studies demonstrated that the costs associated with medication non-adherence in diabetic patients are significant and these costs are mostly driven by inpatient expenditures. Based on this evidence, the potential cost savings that can be achieved by improving medication adherence are substantial (Egede et al. 2012). Statistics show that 20% to 30% of patients do not adhere

to medication regimens that are designed to cure or relieve symptoms, while, the percentage is even higher (30% to 40%) for people who fail to follow regimens designed to prevent health problems. In cases when long term medication is prescribed, the percentage of people that fail to adhere to the prescribed regimen is 50% (Sabaté 2003).

Research studies show that people who are non-adherent require more frequently hospitalisation, which increases health care costs on other services as well. A 2005 study concluded that improved drug adherence to diabetes medicines was associated with a 13 % lower odds of subsequent hospitalisations or emergency department visits. The data predicted that improved adherence to diabetes medicine can avert 699,000 emergency department visits and 341,000 hospitalisations annually, which finally can save up to \$4.7 billion (Sokol et al. 2005).

Figure 7. Adherence and annual spending related to diabetes (Sokol et al. 2005)

Research data taken within the EU member states show that the number of deaths due to misdose and non-adherence of prescribed medication is around 194,500 deaths per year. This issue is also associated with significant costs, where it is estimated that non-adherence cost for EU is €1,25 billion. The statistics performed in United States (US) showed the total direct and indirect healthcare costs which were estimated to be approximately \$177 billion in 2000 (Johnson & Boatman 1996).

The effect of failing to adhere to medication regimens is a common contributor on patient's health and in the worst cases, can even lead to death. There is still a lack of efficient intervention; however, it is recommended that the combinations of indicative measures and interventions have to be used to ensure optimum levels of drug adherence. While some studies suggest to advise and influence government authorities regarding the seriousness of the problem, more research data are needed to conclude about what will be the most successful and cost-effective strategy in the long run (Sabaté 2003).

Studies suggest that people who suffer from diabetes face difficulties for managing their medication regimens and other self-management related factors. As a consequence, diabetic patients in most cases take less medication than the amount needed, including both Oral Hypoglycaemic Agents (OHA) and insulin. Some studies concluded that electronic monitoring systems were useful in improving adherence for individual patients. A monitoring system for insulin administration could inform healthcare providers to understand the patient's needs and offer better support (Cramer 2004).

Recent studies performed in the US show that one-third to one-half of all patients in the US do not take their medications based on instructions, do not use them in the recommended time or in proper doses. The reasons for non-adherence vary from behavioural, attitudinal or economical. Figure 8 shows some of the reasons for non-adherence which include patient lack of understanding about medical conditions and medications, inability to pay for prescriptions, attempts to avoid side effects, or just plain forgetfulness (Omniceil 2014).

Figure 8. Summary of reasons for poor medication adherence (Omniceil 2014).

The medication adherence can be improved by understanding the reasons why patients fail to take the prescribed medications. Indeed, this process is complex and is influenced by a number of factors and determinants, depending on the environment in which people live and the healthcare providers practice and deliver care.

These determinants can be categorised into three different groups: patient related, provider related and external factors (Osterberg & Blaschke 2005). Patient related factors are also categorised further into demographic, socio-cultural and behavioural factors (Krueger et al. 2005). There are also external factors including: disease

characteristics, medication properties and system components. Figure 9 shows the relationship of patient, provider and external factors (Iuga & McGuire 2014).

Figure 9. Determinants of medication adherence (Iuga & McGuire 2014).

Many authors state that patient adherence is a complex issue and many existing strategies are too complex and sometimes not even practicable for physicians. In an attempt to simplify strategies that can be translated and applied to patient care settings, the necessary interventions are grouped into six categories (Ashish Atreja, Naresh Bellam and Susan R. Levy, 2005):

1. Simplifying regimen characteristics
2. Imparting knowledge
3. Modifying patient beliefs
4. Patient communication
5. Leaving the bias
6. Evaluating adherence

Several studies state that standard interventions can improve patients' adherence, however, the existing evidence shows that the effectiveness of some interventions is inconsistent. The reason is mainly due to variations in study populations and methods. Behavioural interventions are considered a good option to use in practice and they can also improve the patient adherence to medicines. Results have shown

that implementing one of these interventions can make significant improvements on patients' health even though such interventions can cost time and money (Heart Foundation 2011).

Recent researches, produced within the Action Group A1 on Prescription and Adherence to Medical Plans of the European Innovation Partnership on Active and Healthy Ageing, have focused on understanding the complex behavioural factors involved in adherence, and concluded there are still no "gold" standards for measuring a care plan's adherence in chronic diseases ((Giardini et al. 2015), (Costa et al. 2015)).

2.6 Behavioural intervention

A variety of research reviews have shown that behaviour change interventions can help improve health outcomes. By using well-accepted intervention strategies, such as recommending effective self-care regimens and educating patients, these can support patients in performing necessary self-care behaviours. There is a proposed group of interventions for successful behaviour change in patients designed to improve health outcomes. Four categories of factors should be the target of behavioural change interventions in diabetes (Peyrot & Rubin 2007):

- Motivators
- Inhibitors/facilitators
- Intentions
- Triggers

Research data shows that despite the number of interventions designed, many patients with diabetes and those at risk of diabetes, have reported their knowledge, attitudes, and behaviours in surveys towards the health care recommendations and diabetes, but often fail to translate these positive traits into healthy behaviours in diet, exercise and weight loss. Such findings highlight the need for better strategies to fill the gap between knowledge and attitudes vs. healthy behaviours (Green et al. 2007). It is well documented that problem solving is one of the seven core diabetes self-management behaviours and is often used as an intervention method within diabetes education and care. Evidence shows that in many cases, interventions with a problem solving component provides positive outcomes and is considered effective in disease control, self-management behaviours, self-efficacy and quality of life (Schumann et al. 2011).

Studies have also confirmed that physicians can motivate patients with T2DM for a long term treatment by designing and using a counselling strategy. Individual behavioural approaches can be used by physicians in their daily outpatient practice to promote the adoption and maintenance of, for example physical activity.(Di Loreto 2003). Other studies demonstrated that a Multiple Health Behaviour Change (MHBC) intervention focusing on diet, exercise, stress management, and social support provided multiple benefits on biological, behavioural, and psychosocial outcomes after the two years of implementation (M. et al. 2011). Even though little information is available about which methods are endorsed to support T2DM in achieving an appropriate physically active lifestyle, behaviour intervention targeting physical activity produces long term glycaemic control.

Statistically significant increases in objective and self-reported exercise, including clinically significant improvements in HbA1c in patients with T2DM have been shown. It has been concluded that behavioural interventions support exercise and life style improvements and depending on the specific behaviour technique, utilisation of theory and intervention can produce clinically significant improvements for a long-term glucose control (Avery et al. 2012). Similar results were obtained by investigating the effectiveness of physical activity engagement in promoting exercises in people with T2DM. Results confirmed the difference in physical activity between the control and experimental groups, with increased levels of physical activity in the experimental group. Confirming that counselling is effective in supporting physical activities, physiological and biochemical parameters and also helps patients manage other potential risk factors and disease (MacIntyre et al. 2004). However, it is important to emphasise that different behavioural change techniques may be required to initiate changes in different target behaviours. The data suggest that there are no single behaviour interventions that can work in all cases and therefore, clinical care teams should have an array of behavioural change techniques available and find the most effective combination. It was shown that at least from behavioural change techniques: prompt focus on past success, barrier identification/problem-solving, use of follow-up prompts and providing information on where and when to perform physical activity, have significant associations with increased levels of physical activity. This is an indication that clinical care teams can optimise their consultations by incorporating specific behaviour change techniques which are closely associated with increased levels of physical activity and long-term glycaemic control (Avery et al. 2015).

While behavioural intervention is mainly focused on supporting individuals during face to face consultations or through traditional media such as leaflets; mobile phones and technologies have the potential to transform the delivery of health

messages. For example, regular text messages can be sent to people with diabetes to sustain their motivation and also other advice when it is necessary (Free et al. 2013). Studies revealed that utilising information technology, such as internet and mobile phones, holds great promise in enhancing diabetic care. Results show that HbA1c levels as well as self-efficacy scores were improved in the intervention group after sending them daily messages via mobile phone, prompting them to enhance their diabetic self-care behaviours (Faridi, Z., Liberti, L., Shuval, K., Northrup, V., Ali, A., & Katz 2008). Another similar study showed promising results later evaluating an approach to insulin titration using text messages and phone calls among patients with insulin-dependent T2DM (Levy, N., Moynihan, V., Nilo, A., Singer, K., Bernik, L. S., Etiebet, M. A., ... & Natarajan 2015). Text messages act as a reminder to patients to check their blood glucose levels and can be automated to be sent to the patient at a given time of day. Text messaging also provides a simple and quick way for patients to send their blood glucose data to the clinician from any location, given their phones are able to send text messages. Finally, results showed preliminary potential of these apps to change behaviours and, subsequently, health care, and addresses the need for further research on mobile health interventions for diabetes and other CDs. Research is especially important for low-income populations who face numerous challenges in managing chronic illness.

2.7 Technology background

In today's world, technology capabilities are supporting patient's needs in the ways that we have never seen before. Patients have the chance to find potential treatment options online, proactively following up about test results and directly participating in care decisions and researching over-the-counter and non-traditional remedies on their own. No doubt that over the next year, and likely years to come, this increased patient engagement facilitated by technology will continue to change the ways patients and providers interact (Susan C. Hull 2015). These advances have also provided physicians with better information to diagnose and treat patients which improved the quality of life and saved people's lives. Areas like biotechnology, pharmaceuticals, information technology, the development of medical devices and equipment, to name but a few, have all made an incredible impact on improving the health of people all around the world. Recent innovations in tele-health services, mobile technologies like tablets and smart phones, as well as the use of electronic medical records have brought new advantages for both physicians and patients. Patients and doctors are connected thousands of Kilometres away through telecommunication. Mobile devices on the other hand also provide unique chances to access any type of information that physicians need – from drug information, research and studies, patient history or records. Other advantages in medical

equipment like X-rays, and CT scans also have changed and improved many examination and diagnostic capabilities (Healthcarebusinesstech.com 2014).

Compared to the limited data points that were available in the past on which medical researchers could base their hypothesis, in today's digital world the amount of health data that is available is substantially, and continues to grow, and medical personnel and researchers are, and will be able to use a terabytes of data for analysis. Some of the other benefits from health care modernisation systems are the use of rapid-learning health networks to determine the effectiveness of a particular treatment for a certain population or to better understand side-effects of a drug. There is no doubt that the need to involve the informatics sector in health care has been recognised at the local, national and international levels. In 2005, the WHO adopted Resolution WHA58.28 to establish an eHealth Strategy that noted the "potential impact that advances in information and communication technologies" could have on medical research (Castro 2009). However, the full potential of the technology in medical practice has yet to emerge. The rate of development and proliferation of information and communication technologies is increasing and it is expected that the human computer interface will sophisticate even more. In the future more efficient voice and handwriting recognition is expected, increasing applications of tele-surgery, more sophisticated undergraduate and postgraduate computer-based training; and better structuring and portability of integrated electronic health records. Together with technological advances, the challenges for health professionals will increase, where they should be able to use the new power at their disposal for the benefit of their patients (Hutton 1996). In order to meet these challenges, tremendous changes should be implemented in educational content, teaching methods and philosophy, and higher medical education.

The rapid evolution in health informatics is a new potential power to improve the quality and efficiency of care for these disorders. Results show that information and communication technologies are essential for support and care of people with CD. It is an integral part used in the management of chronic illness to facilitate shared services (virtual health networks and electronic health records), for better knowledge management, as well as consumer-based health education and evidence-based clinical protocols. Some of the most usual benefits of such technology is monitoring vital signs of patients with CDs and replacing home visits by nurses in person with telemedicine videophone consultations (Celler et al. 2003). Existing consultation methods used to monitor these conditions place a considerable strain on health service resources. The focus now is placed on utilising the information technology to help manage patients (Adler-Milstein et al. 2007).

Due to a variety of IT services and products available, their implementation and integration in health system requires substantial changes, design and they must be managed effectively by hospital and practice leadership. According to the Agency for Healthcare Research and Quality (AHRQ) of U.S., the following technologies are helpful in CD management programmes (Agency for health care research and quality 2014):

- Clinical decision support
- Health information exchanges
- Disease registries
- Patient-centered applications
- Electronic health records
- Telehealth

Information and communications technologies (ICT) are bridging gaps in the health systems, as well as facilitating and managing the flow of information related to the growing number of CD patients.

It has a central role for an integration and co-ordination of electronic health information that provides timely, relevant, reliable, and secure health care information and services. It is also very efficient and supportive in remote delivery of chronic care services, enabling technologies used in application development including video phones, messaging and reminder systems, measurement and monitoring, and personal computing devices, which enable connection of peripheral medical devices that can use the information and facilitate the transmission of physiological data and images. Figure 10 shows the convergence of ICT to support CDs management (Public Health Institute 2010).

Figure 10. ICT convergences in CD management (Public Health Institute 2010).

One important contribution to the management of CD is the Information Technology in Diabetes Management (ITDM). The ITDM aims at improving processes of care, prevents diabetes complications and helps to manage better the costs. Research shows that one of the most significant benefits of ITDM are the diabetes registries. This process provides efficient communication; improves the synthesis of information and delivery of knowledge. These benefits enable the co-ordination of care which helps patients to receive recommended care, and provides tools and information that is necessary for more effective self-care. Furthermore, the approach is also effective due to the influence on behaviour at three locations: at the health care system level, at the point of care through reminders, and at the patient's home (Davis Bu, Eric Pan, Janice Walker, Julia Adler-Milstein, David Kenderick, Julie M. Hook, Caitlin M. Cusack, David W. Bates 2007).

There is solid evidence that State-of-the-art technological solutions are creating new ways for better management of diabetes. They are assisting health care professionals and patients during the insulin therapy process, by helping patients understand their disease. They also provide a safe environment for the patients by monitoring adverse and potentially life-threatening situations with appropriate crisis management. In diabetes in particular, the technology platforms require more frequent measurements and data entry. However, studies have shown that some important parameters that affect management conditions such as: emotional and psychological stress, physical exercise, and variability of daily life, require more efforts to define, monitor, predict, and account and are more complex. Based on such results it is clear that new technology services should take into account some of these parameters and this would provide significant advantages in the future, com-

pared with services that only use glucose measurements and food intake. Moreover, all participants agree that the amount of information required from them to be recorded, as well as ease of use of the services have more chances to be accepted. Figure 11 shows one example of the developed platform that provides integrated, professional management and therapy services for patients with diabetes (Spanakis, E. G., Chiarugi, F., Kouroubali, A., Spat, S., Beck, P., Asanin, S., ... & Thestrup 2012).

Figure 11. A chronic care model that supports separation of activity spaces of the information care space developed to serve diabetes patients (Spanakis, E. G., Chiarugi, F., Kouroubali, A., Spat, S., Beck, P., Asanin, S., ... & Thestrup 2012).

Diabetes management using IT reduces other complications including blood sugar level. For example, through ITDM, the blood sugar level can be better controlled with strict dietary compliance and as a result the damage to small blood vessels throughout the body will be lessened. Improving vascular diseases helps lower the rates of other diabetes complications such as: blindness, lower-extremity amputations and end-stage renal diseases (Adler-Milstein et al. 2007).

Using particular IT systems in hospitals is considered a major organisational commitment that will last for several years. The new IT systems also affect how physicians need to make substantial changes to how they practice medicine. In order to use the full benefits of the system, physicians must devote considerable time to training and personalising the system, as well as adapting their work processes. While there are so many options available, providers must choose the most efficient option among them all. Indeed, rapidly developing technologies, and the vast number of choices makes providers concerned about buying the wrong kind of system for their practice, acquiring technology that has already become outdated, or purchasing a poor-quality system (Office 2008).

2.7.1 Telemedicine

Telemedicine is focused on delivery of healthcare via ICT. It is often used as a broad term that also includes “telehealth,” “e-health,” “mobile health,” and “connected health.” Several studies have reported that new advances in ICT and telemedicine in particular can improve the access to health care, improve the quality of health care delivery, and reduce health care costs. There are several telemedicine technologies available including telephones and Smartphones, video conferencing, manual and automated data entry, point-to-point connections, autonomous equipment, and wearable or implantable devices.

The integration of telemedicine into healthcare adds great value in managing CD both for patient and provider. Research studies show that this type of technology is making a difference in everyday CD management. As mentioned above, telemedicine technologies used in CD management are diverse; however, their primary role is to(Shiva Gopal Reddy 2015):

- Provide education to consumers to improve self-management
- Enable faster, cheaper and instantaneous transfer of health-related information via tele-monitoring
- Facilitate communications between patients in rural and remote areas with healthcare professionals
- Improve Electronic Health Record (EHR) management

Telemedicine is considered more as a tool that can provide additional advantages and help health providers to extend the traditional practice of medicine. The main benefits of using telemedicine is to help transform healthcare itself by encouraging greater consumer involvement in decision making and providing new approaches to maintaining a healthy lifestyle. For example people with chronic illnesses can avoid expensive visits and hospitalisation using telehealth devices to monitor their conditions on regular basis (Association 2006). Remote monitoring is an example that helps CDs patients avoid hospitalisation and enables those in geographically isolated settings to access specialised and preventive medicine. This type of monitoring is essential and contributes significantly to patients with CDs because any change in vital signs can signal a need for medical intervention. Providing the data on a regular, real time basis is an advantage that can prevent the hospitalisation by identifying and treating problems in care before negative trends reach crisis stage. The presence of two way video monitoring programmes can further enhance the quality of interaction between patient and caregiver and in this way helps patients

to follow the treatment with better consistency (Litan 2008). Evidence shows that telehealth is innovating diabetes care by providing tighter glucose control, improved clinical outcomes, reduced hospitalisations, and closer screening that prevents or arrests development of serious complications. As an automated support tool for patients with diabetes it helps both patients and health care providers to make better decisions. This system is developed to organise six types of uploaded objective and subjective data of interest to managing diabetes:

- Patient-collected physiological data, such as blood glucose levels, continuous glucose levels, and blood pressure
- Laboratory data, such as HbA1c or lipid levels
- Behavioural information, such as dietary intake and exercise patterns;
- Medication dosages, allergies, and other history
- Subjective symptoms of hypoglycaemia or other complaints
- Pertinent event data, such as emergency room visits, hospitalisations, scheduled ophthalmology visits, vaccines, and missed clinic appointments
- Images of retinal photos, wounds, or other structures (Klonoff 2009)

Telemedicine is contributing to diabetes management from different approaches. Starting with basic interventions which include educational websites, nurse call centres, video phones, and telephone case management using clinical practice management protocols and recently providing more advanced applications. Recent developments in technology have developed a wide variety of advanced applications in diabetes management. One example is an advanced application that is providing patient education, counselling, and nutritional support through the use of video conferencing. Other services enable the use of digital glucometers along with internet-based disease management portals and retinal imaging capabilities. From voice and e-mail to high-resolution images and video, their diabetes is more controllable and more people are living normal lives (Blanchet 2008).

Despite the advantages offered by this type of technology, there are obstacles present during implementation and application of telehealth in different situations. Many industries have already adjusted their business models with internet, mobile technology and other digital advancements; the health care industry has proceeded carefully due to the unique obstacles that it is facing. A physician who contacts a patient through telehealth in another state or country must comply with the rules

and regulations of the state or country where the patient is located, such as the licensing and prescribing laws of that state or country. Considering the unique rules and systems in different parts of the world it is difficult for physicians to check the current or pending legislation in that particular part of the world. The services provided by telehealth transmit electronically sensitive data about the patients which is a new risk of privacy. This is a new challenge for health care organisations to establish rigorous security systems for protection. The security should be also efficient for the data stored on telehealth devices (Ernst & Young LLP 2014).

2.7.2 Mobile Health

Application of mobile technologies in health care and public health practice is increasing which offers a new practice for communication, monitoring and education as well as coping with challenges in CD management. The popularity and technological feature of mHealth has a strong potential to influence CD management around the globe. Most people today own a mobile phone and this is an opportunity to monitor symptoms and connect patients with providers outside of health care facilities (Hamine et al. 2015).

Mobile health offers the chance to capture multiple sources of health data such as information about the subjects' physical activity, location and travel areas, physiological responses (using small sensor technology that can be attached to the body and connected wirelessly to the telecommunications network); and activities (e.g., through text messaging surveys) over extended periods of time. This type of technology can have a large scale impact in health care through accessibility and data availability. Examples include, decreasing the number of people with diabetes and helping people who need medication to take them as scheduled (Crews et al. 2013).

Mobile health is bridging the gap between patients and clinicians and overcoming the common barriers of language, transportation and financial considerations. For example, diabetes patients who may miss their education appointments or materials, can receive the educational support in the right format, at the right time using mobile technologies. The benefits are even more beneficial for rural patients who must travel a long distance to see a physician and have real access to healthcare. However, in the case of mobile health, providers can send daily or weekly texts or emails, including general educational messages, diet and exercise tips, and information about local healthcare resources (Jonathan Javitt, MD 2014).

The expansion of mobile health technologies is also considered as the answer to keeping diabetic patients under tight control. Recent review articles demonstrated that the most common types of diabetes apps identified were for health tracking

or self-monitoring tasks. One study showed that around 33% of apps are focused on health tracking blood sugars, insulin doses, and carbohydrates. Other groups are focused on teaching/training apps (22%), food reference databases (8%), social blogs/forums (5%), and physician directed apps (8%) (Eng & Lee 2013).

Mobile phone messaging is also an alternative to provide valuable advice about lifestyle modification. While the literature suggests that lifestyle modification is important to prevent T2DM diabetes, the mobile phone messaging that encouraged lifestyle change could reduce the incidence of T2DM. The existing evidence supports the opinion that mobile phone messaging is an effective and acceptable method to deliver advice and support towards lifestyle modification and help to prevent T2DM. Indeed, together with advances in technology new methods for measuring and controlling glucose levels and other important parameters are becoming more simple and convenient. The existing and emerging apps have a good usability and functionality at nominal or no cost. For example, apps such as Diabetes Log, provides the main essentials for diabetes monitoring for free, while users can have additional features by paying for another type of app, such as Diabetes Buddy. Some of the existing apps offer other features like storing blood pressure and cholesterol data, and weight management tools. Considering the trends in technology and mobile health in particular the users will have more chances to conveniently track their glycaemic control and overall health, which can ultimately improve their ability to effectively manage their diabetes (Tran et al. 2012).

2.7.3 Medical Devices and Sensors

New innovations in medicine and medical technologies are improving the quality of life. The presence of various technologies such as: minimally-invasive surgeries, better monitoring systems, and more comfortable scanning equipment, enable patient's recovery, and more time enjoying a healthy life. Using such technologies in research provides new advantages and access to diseases on a cellular level. This helps to develop new vaccines against life-threatening diseases like malaria, polio, and prevent the spread of disease and save thousands of lives all around the globe.

Such advances have improved the quality of life and the control of biochemical parameters in people with diabetes. For example, insulin pumps and continuous glucose monitoring (CGM) systems are two technologies that help patients get information about glucose level changes. Studies performed with children with T1DM showed improvements in glycaemic control in those using the insulin pump or sensor-augmented pump therapy (Hirose et al. 2012).

Currently, there are several Continuous Glucose Monitoring (CGM) systems available and compared with relying on urine glucose test strips and a single blood glucose measurement at each visit to the doctor, these devices enabled a degree of blood glucose control that was unimaginable at their inception. They use a sensor that measures the concentration of glucose and is inserted under the skin, to provide readings every one to five minutes. The monitor connected with the device can show the levels of glucose and its trends throughout the day and also sounds an alarm if the level gets too high or too low (Hirose et al. 2012). Application of wireless sensor networks provides vital information which is transforming the way health care is provided. As it was shown in diabetes treatment instead of collecting vital signals only a few times along the day, healthcare professionals can monitor patient records which will provide several improvements compared to current capabilities (Lopez et al. 2009).

Recently, an exciting, new innovation is being tested; it is a biomedical device which is known as the artificial pancreas. The artificial pancreas bridges the gap between two pieces of diabetes technology that already exist: the insulin pump and the continuous glucose monitor. This artificial pancreas device will calculate the amount of insulin that the pump delivers based on a computer program. People who might have it can make dosing adjustments, however, the device is expected to act automatically and keep blood glucose levels within a target range (Erika Gebel Berg 2014). Recent results have shown the use of robots to support and motivate children and to keep a diary.

The test results have shown positive influence of robots in children with T1DM and it was concluded that children shared significantly more personal experiences in their diaries when they were interacting with the robot. Moreover, they enjoyed working with the robot and considered it as a helpful and supportive friend (van der Drift et al. 2014).

2.8 The “Diabetes Market”: current investments and trends

The incidence of diabetes is rapidly escalating across the globe and therefore, the diabetes market is also growing with numerous products at different stages of clinical pipeline and others at different phases of industry life cycle (Research 2015). Advances in technology have a tremendous effect on growth of this market across the globe. In order to meet such increasing demands, investment in the research and developments segment is strongly supported and as a result, several innovative products are under investigation which would be introduced to the market after fulfilling the requirements and criteria set by medical regulatory authorities. The trends show that every year, the number of diabetes drugs is increasing which is an

indication that their market shares are expected to increase further in coming years.

Some recent reports show that the global diabetes devices and drugs market is expected to grow from US\$54,04 billion in 2012 to US\$83 billion in 2019. The whole market is divided in two main lines: insulin delivery devices and diabetes monitoring and diagnostic devices. The diabetes monitoring and diagnostic devices include glucose test strips, glucose meters and continuous glucose monitoring devices. It is estimated that by the end of 2019 test strips will be the leading segment, while the market growth will be more for continuous glucose monitoring devices. The global diabetes devices and drugs market covers four key regions: North America, Europe, Asia Pacific, and Rest of the World. Figure 12 shows the global diabetes device market analysed in 2012 (Research 2014).

Figure 12. Some trends in diabetes device market (Research 2014).

The global health care solutions market is changing due to the presence of mHealth apps which are integrating successfully health care services. The mobile healthcare market is broadly categorised into connected medical devices and healthcare applications; the market is dominated by the connected medical devices which was approximately 80% in 2013. This market is further categorised into cardiac monitoring, diabetes management devices and other types of devices like those for sleep apnoea, respiratory monitors etc. However, cardiac monitoring and diabetes management devices are the main contributors in this market. It is expected that diabetes management devices market will experience significant growth due to increasing global burden of diabetic population.

The main influencers of such growth are: growing adoption of Smartphones, penetration of 3G and 4G network and advances in mobile technology (Reports 2013). In the current market Android and iOS are the dominant mobile platforms for

mHealth developers where the focus on medical conditions group for mHealth apps is currently 6,6%. This group includes apps that track, display, monitor, and share health parameters, medicine intake feelings and provide necessary information regarding specific health conditions such as: diabetes, heart failure and obesity. Figure 13 shows the biggest groups of mHealth apps used (Research2Guidance Free report about health apps & mobile health apps. 2014).

mHealth app category share

Figure 13. mHealth app category share (Research2Guidance Free report about health apps & mobile health apps. 2014).

According to the (Eng & Lee 2013), patients with chronic health conditions are one of the important target groups considered by mHealth app developers. Diabetes is expected to be the main group with the highest business potential for the future. Various apps that support glucose level and insulin tracking have been categorised as the number one app in diseases management. These potential and positive predictions for apps that are used in diabetes is the main reason behind the growing number of developers that have published up to now, with more than 1100 diabetes apps for iOS and Android devices (Research2Guidance The App Market Specialist 2014).

Figure 14, shows the top ranked therapeutic areas for mHealth app publishers (Research2Guidance Free report about health apps & mobile health apps. 2014).

Business potential of different therapeutic areas for mHealth app by rank in 5 years

Figure 14. Top ranked therapeutic areas for mHealth app publishers showing the diabetes market in first place (Research2Guidance Free report about health apps & mobile health apps. 2014).

Research data shows that the percentage of diabetes apps used for different diabetic needs are: teaching/training apps (22%), food reference databases (8%), social blogs/forums (5%), and physician directed apps (8%) (Eng & Lee 2013). However, it is important to emphasise that there are some barriers, such as lack of data security (34%) and standards (30%) which can prevent a market momentum.

2.9 Conclusions

Several examples have shown that having a long term, or chronic illness affects the appearance, physical abilities and independence of individuals.

In other words, successful interventions early in life were shown to have the potential to reduce substantially the CD pandemic. Patient-centred technologies appear to be effective for more efficient and effective support of older individuals and improve CD management. Another factor contributing to CDs was considered - ageing. Literature concluded that the world population is experiencing significant ageing and increasing the proportions of older people in the total population. This is considered to have profound consequences on a broad range of economic, political and social processes. It was concluded that as the population is growing, aging, becoming more obese with less physical activity, the number of people with diabetes is increasing. Data have shown that in the European region, the prevalence of diabetes continues to increase resulting with more disabilities and enormous health care costs.

The influencing factors responsible for such increase in Europe are considered to be overweight and obesity, unhealthy diet and lack of physical activity. Research has shown that diabetes can cause a number of other complications and health problems in people. The evidence provided supports the findings that glucose levels can also cause other serious diseases that affect the heart, eyes, feet, kidneys, nerves and teeth. It is important, for people with diabetes, to control cardiovascular diseases, kidney diseases, eye diseases, and diabetic foot pathologies. Another factor that is believed to prevent diabetes related complications is also early diagnosis. For this purpose, several testing techniques and methods are developed which can help prevent complications and improve the glycaemic control as the main factor in diabetic complications. Based on such facts, the management strategies based on dietary therapy, increased physical activity, and drug treatment in use appear to be very beneficial. Statistical data provided from various authors and papers show non-adherence is a very serious problem that contributes to diabetes complications. It was mentioned that 20% to 30% of patients do not adhere to medication regimens that are designed for cure or relief of symptoms, while, the percentage is even higher (30% to 40%) for people who fail to follow regimens designed to prevent health problems. The main conclusion from different studies is that interventions can improve patients' adherence, however, the existing evidence shows also that the effectiveness of some interventions is inconsistent. The reason is mainly due to variations in study populations and methods.

Several representative examples were chosen which show the efficiency of recent innovations in telehealth services, mobile technologies like tablets and smart phones as well as the use of electronic medical records that have brought new advantages for both physicians and patients. Some of the most usual benefits of such technology are: monitoring vital signs of patients with CDs, replacing home visits by nurses in person with telemedicine videophone consultations, preventing diabetes complications and helping to manage the costs, reducing other complications including blood sugar level. The integration of telemedicine into healthcare appeared to provide value in managing CD both for patient and provider. The technological features of mobile phones and mHealth presented have strong potential to influence CD management around the globe. It was shown in several examples that mobile health offers the chance to capture multiple sources of health data such as information about the subjects' physical activity, location and travel areas, as well as physiological responses over extended periods of time. Some examples presented have shown that mobile health and behaviour interventions are important to prevent T2DM. Examples show that mobile phone messaging is an effective and acceptable method to deliver advice and support towards lifestyle modification and help to prevent T2DM. It was demonstrated to be very helpful to conveniently track glycaemic control and overall health, which can ultimately improve their ability to effectively manage their diabetes. From a clinical point of view, the diabetes mellitus diagnosis is based on classic symptoms of patients such as: (i.e., polyuria, polydipsia, polyphagia, weight loss). The literature also mentioned other signs and symptoms that may suggest hyperglycaemia which include: blurred vision, lower extremity paraesthesia, or yeast infections, particularly balanitis in men. It is evident throughout the chapter that there are certain challenges and barriers in treating and managing the health of people with diabetes. Examples show that depression is the most difficult barrier in patients with diabetes. Bi-directional relationship between depression and diabetes increased the risk of people who are depressed developing diabetes and at the same time, patients with diabetes have higher risk of depression.

Many examples illustrated with graphs and tables have shown recent investments and trends in CD and diabetes in particular. It was concluded that as the number of diabetes drugs is increasing, their market shares are also expected to increase in the coming years. New and significant contributions in such market change are the presence of mHealth apps which are integrating successfully into health care services. Currently there are more than 1,100 iOS and Android apps that are specifically designed for diabetics and healthcare professionals. Various apps that support glucose levels and insulin tracking have been categorised as the number one app in

diseases management and in the future this is expected to be the main groups with highest business potential.

Chapter 3

Adherence in diabetic disease

Increasing medication adherence is a cost-effective approach to improving health outcomes and lowering healthcare costs. Diabetes patients who are medication adherent are 48 percent less likely to die prematurely (Ho et al. 2006). Care improvements for enhancing adherence include patient engagement and education. This can be achieved through effectiveness interventions able to reinforce patients' motivation and to drive them into proper disease self-management.

The first part of this chapter is dedicated to motivation, self-management and engagement as a means to reach adherence in diabetes. Then state of the art behavioural change theories and models applied to diabetes are described. Finally the chapter analyses the mHealth solutions applied to diabetes and in particular the ones based on behavioural interventions.

3.1 Factors influencing diabetes adherence

3.1.1 Motivation in Diabetic Patient

In general, the need for motivation is universal and almost all groups of people could benefit from having more motivation. This need isn't limited only to those with diabetes; however, people with diabetes face more specific challenges because they never get to take a break from their diabetes management. As a result, a lot of techniques are employed to motivate the person with diabetes to take better care of their health, but it is difficult to maintain a high level of motivation day after day (Dixon 2008). Lifestyle risk factors are now considered as the main contributors to morbidity and mortality in Europe. The traditional motivation methods still used in the practice of health consultations rely on providing direct advice information. This information is important for education and informing consumers but it is not enough to make significant behavioural changes (European Food Information Council 2014). In case of diabetes many patients have a high ability but low motivation; therefore, there is a great need to increase the motivation in order that they cross the behaviours activation threshold (Fogg 2009). However, scientists argue that it is important to understand each person's unique perspectives and priorities when starting with a treatment strategy to encourage empowerment and behavioural change. Careful intervention has a positive impact on people and results have shown that some individuals felt empowered to make lifestyle changes related to nutrition and exercise, and therefore, their ability to cope with challenges improved (Dellasega et al. 2010). Motivational interviewing is an alternative that has been successful with very resistant clients. Results show that this type of motivation is effective in a wide range of problem behaviours, especially where improved patient compliance is a priority. Some authors mentioned a series of moti-

vation levels called “Stages of change”. For example, in the Stage 1 and 2, individuals think about the change and have many doubts, in Stages 3 and 4, individuals are ready to change and start actively making some changes. In the last stage, maintenance, individuals sustain the behavioural change (Scales & Miller 2003). There are also some contradictory results about the effect of motivational interviewing as a centred counselling technique in patients with T2DM. Motivational interviewing showed lacklustre results in improving clinical outcomes in patients with T2DM. It was concluded that this method only has a short time effect in glycaemic control, and in practice is very time consuming in that it requires significant efforts from health care providers (Dickey 2012). It is important to mention however, that the majority of studies support the opinion that motivational interviewing has the potential to facilitate change and improve efficacy and engagement alongside other interventions. In many cases the professionals managed to deliver motivational interviewing effectively however, it is still unclear as to what aspects of motivational interviewing are being delivered. It is evident that this type of motivation is more effective when more sessions are delivered using an individualised approach (Christie & Channon 2014).

For diabetic patients the quality of life is strongly associated with regular physical activity. Epidemiological studies has shown that physical activity reduces by 30-50% the risk of developing diabetes than do sedentary persons (Bassuk et al. 2005). Therefore, it is essential to use motivational methods to promote physical activity in people with diabetes. This can be performed by increasing patient education especially for high-risk patients. A randomised, prospective study was conducted using a large number of patients to understand the role of education and teaching intervention to motivate patients to gain expertise and closely follow their risk parameters. Results showed that the cholesterol and HbA1c values were significantly lower in the case of intervention compared with control. Patients who have adequate information were more successful in maintaining good control of their risk factors, resulting in a slower progression of diseases. A similar study showed promising results when patients were informed and invited for consultation to a diabetes clinic in an academic hospital. By teaching and motivating patients to control their risk factors, it was possible to reduce cardiovascular risk and a slower progression of microvascular disease (Rachmani 2005). Besides motivation, educational programs can also have other roles in diabetes problems. In fact, studies have concluded that good educational programs have many beneficial effects on the patients’ knowledge about diabetes, improving patients’ self-efficacy and result in some belief changes for patients with diabetes and associated risks, such as microalbuminuria (Li et al. 2011).

One method that is constantly growing and supporting the patients during their daily lives is the use of ICT. This strategy uses the pedometer and a mobile phone. The pedometer measures and extracts the information and sends it to the mobile phone. Once the data are received they are submitted to the specific system which offers the possibility to view all information on the phone. In this way, a reciprocal relation between the patient and the system is developed which is one of the key elements of the motivation strategy (Morandi & Serafin 2007). This type of system based on ICT is improving the accessibility of people with diabetes in many countries where the number of care centres and medical staff is reduced. For example, using mobile and web technologies it was possible to overcome geographical barriers and increase the health care service. It enables diabetes patients to manage their own lifestyle data around the clock using their mobile devices (Android, iPhone, and iPads) and/or web-based applications. The platform also enables medical care personnel to access patients' data through a protected web portal (Takenga et al. 2014). Another multidisciplinary project was proposed to promote and motivate healthy lifestyles using assistive technology. The project is represented by an ICT system and allows providing tailored interventions to the users through their smartphone in order to motivate them. The main advantage of the system is developing a virtual individual model for user characterisation, which is based on physical, functional and behavioural parameters selected by experts. Using a mobile phone the digitised and updated parameters are used for detection of activity and nutrition habits and then the information is used for personal feedback. In order to be more effective, the user interface will integrate various attractive games to promote effective health literacy and facilitate behaviour change (Carrino, S., Caon, M., Angelini, L., Mugellini, E., Khaled, O. A., Orte, S., ... & Rizzo 2015).

The benefits of using text messaging for diabetes motivation were beneficial also in countries that are not well developed. Studies designed and applied in such cases showed how mobile phone technology can be used in a simple but intelligent way for diabetes programmes in a variety of settings. In the TEXT4DM study, a large number of participants, who were under normal diabetes care, received mobile phones. The tested groups received Short Message Services (SMS) with the main information about different dimensions of diabetes self-management such as advice related to diet and exercise, self-monitoring and how to handle emergencies. The evaluation of different mechanisms influenced by a participant's usage of mobile technology for diabetes showed that The TEXT4DM is indeed an enriching experience in many ways. The text messaging practices proved to be helpful for enhancing motivation, diabetes care knowledge as well as other contexts (Olmen et al. 2014).

Another study showed promising results by using technologies to motivate patients to improve their health outcomes. A patient-centred, computer-assisted intervention developed was supportive for improving diabetes self-management capabilities. It was shown to influence the patient's perception that their conditions are supported, which changed perceived competence. Results support the finding that the self-determination model for health behaviour change and the chronic care model can be successful to motivate patients to improve their health outcomes (Williams, G. C., Lynch, M., & Glasgow 2007).

A new model proposed for automatic generation of messages to increase motivation presents in a comprehensive way the basic aspects of motivational messages. According to this model basic aspects of motivational messages are:

- Time
- Intention
- Content
- Presentation

Figure 15 shows the four components of the model of motivational message (op den Akker et al. 2015).

Figure 15. Motivational messaging model showing four important components that can influence the health conditions of people with diabetes (op den Akker et al. 2015).

Other examples show the effects of interface design and feedback in behaviour change support systems. Successful application of such systems is based on principal features such as: personalisation or tailoring, context-awareness, feedback and interaction. Different forms of feedback presentation have shown to work in some users; however, they do not have always the positive effect on adherence. Finally, it is recommended that for personal motivation, more personal and context-aware

feedback, more variations as well as the possibility for more interaction with the coaching system is needed (Klaassen et al. 2013).

A more comprehensive study in India, showed that sending text messages can increase the motivation of patients and is an effective way of preventing the development of T2DM in at-risk men. Using a large number of participants it was possible to conclude that short messaging service (SMS), which consisted of 2 to 3 messages sent twice a week for around 2 years, increased the motivation and chance for better management by 36% (Nainggolan 2013).

While many diabetes interventions that are present today are focused on biologic and behavioural factors, such as symptoms, diet, and physical activity, it is also very important to take into consideration the influence of other physical and social environments such as: low income, employment insecurity, low educational attainment, and poor living conditions, on health outcomes. For example, the conditions in which individuals are born are known to have a relationship to the incidence of T2DM and at the same time these parameters present an opportunity to improve health conditions of diabetic patients. The results have shown that by using the data regarding social determinants would improve the ability of clinicians and health systems to engage and to treat patients with chronic conditions, such as T2DM (Hill et al. 2013). Mobile phone based education is proposed also as an intervention method for the reduction of stress among diabetic patients. In a study of (Patnaik et al. 2014), two groups of participants were used (control group and test group) with different educational materials. Results showed that the test group that received intense lifestyle education (using both printed materials and computers) and were contacted by telephone and SMS every 3 weeks for 3 months significantly decreased their stress score. Further research showed that mobile-based education has great potential to improve patient mental status and increase patient-provider communication, and to decrease stress. Nowadays diabetes education can also be administered through telemedicine. In other research, 56 participants with diabetes were observed the effect of diabetes education in person (control group) and via telemedicine (telemedicine group). Based on the patient's satisfaction in the telemedicine group, this methodology was equally effective in improving glycaemic control, compared with education in person (control group) and both methods were well accepted by patients. Indeed, various proposals were presented and developed for the diabetes motivation and support. Similar with telemedicine, a telephone peer-delivered intervention to enhance self-efficacy in T2DM was developed and tested. Diabetic patients received a motivational telephone support from a diabetes specialist or a supporter for more than 6 months. The results showed that patients with poorly controlled diabetes accept the value

of telephone support, even though the approach appeared limited in some cases (Dale et al. 2009).

According to recent results this intervention method can be effective for improving glycaemic control. However, although results have proved that telephone intervention was positively associated with glycaemic outcomes in diabetes, it was evident that the change was not different compared with standard clinical care in improving glycaemic control in diabetes. Finally, this is especially beneficial for low-and middle-income countries (Suksomboon et al. 2014).

Scientists have made conclusions based on social cognitive theory regarding the self-efficacy and autonomous self-regulation complementarily in diabetes motivation. Results provided the evidence that self-efficacy and autonomous self-regulation, work in a complementary way and both of them appear to make independent contributions to the prediction of both dietary self-care and life satisfaction. While self-efficacy is considered as a better predictor of self-reported adherence to dietary self-care activities, autonomous self-regulation showed better results as a predictor of life satisfaction. This supports the conclusion that, whether one feels happy in life is related to whether those self-care activities have personal significance (Sentcal et al. 2000).

3.1.2 Engagement

The National eHealth Collaborative partnership defined in 2012 the patient's engagement as: "Actions individuals must take to receive the most benefit from the health services available to them" (National eHealth Collaborative 2012). Patient engagement refers to knowledge, skills, ability, and willingness to manage the patient's own health care. This concept combines different definitions such as patient activation and similar interventions designed to promote positive patient behaviour, such as obtaining preventive care or exercising regularly (James 2013).

Measuring the engagement of a patient during a medical treatment is difficult. The most well-known measurement is the "Hibbard's patient activation measure", which identifies and measures four components of patient activation (Hibbard et al. 2004):

1. Locus of control (or the belief that the patient is responsible for and can affect their own health);
2. Knowledge (of health and health problems);
3. Confidence (in the patient's own ability to manage their health, interact effectively with providers, and adhere to treatment plans);

4. Action (the extent to which the patient is adhering to treatment plans).

Incorporating patient engagement strategies in patient treatment intervention has been shown to have a positive impact in adherence. Due to the complexity of modern health care, patients often struggle to obtain, process, understand and communicate health information and services. Many patients lack health literacy, or a true understanding of their medical conditions. Most patients ask for (Coulter, 2005):

- Security of knowing that they will be able to access timely, reliable, effective, and safe health care when they need it
- Receive adequate information and support to participate in decisions that affect them
- Empathy, dignity, and respect from clinical professionals
- Be involved on the options for being treated, while taking into account their preferences
- To not worry about the financial consequences of being ill.

These issues illustrate how there are many aspects that must be dealt with related to patient engagement. Carman et al., (2013), proposed a framework that conceptualises the engagement in three main levels (Figure 16).

Figure 16. A Multidimensional Framework for Patient Engagement in Health Care, (Carman et al. 2013)

The first level is based on patient care: patients receive information about a condition and answer questions about their preferences for treatment. This level of engagement aims at improving both patients and caregivers to make decisions based on the medical evidence and patients' preferences. The second level of engagement is focused on health care organisations and consumer inputs in order to ensure being as responsive as possible to patients' needs. Finally the third level involves consumers in the decisions taken from communities and society regarding laws and regulations in public healthcare.

One strategy consistent with the first level of engagement described by (Carman et al. 2013) is shared decision making. This approach foresees that patients and physicians share information on the patient's condition, treatment options and medical evidences, as well as the benefits and risks of treatment. This allows taking into account patients' preferences and related treatment plan. In line with the second and third levels of engagement, there are new approaches where healthcare organisations strive to meet patients' needs and preferences.

There are several factors that may need to be overcome to carry out effective patient engagement and activation strategies. Some of these issues are attributable to patients while others to care providers. In order for a patient to engage effectively in self decision making, they need to have a certain degree of health literacy. While people with higher health literacy levels demonstrate healthier behaviours, are more adherent to treatment, report less chronic illness, feel healthier, and live longer (Sanco et al. 2013), people with poor literacy are less able to obtain, process and understand information about healthy living and self-regulate existing medical conditions (Morrisroe 2014). The European Health Literacy project (The HLS-EU Consortium 2012) measured how people access, understand and apply information to make decisions in terms of health, disease prevention and health promotion. According to the study outcomes, 12,4% of adults were found to have inadequate general health literacy and 35,2% with problematic health literacy. Yet although low health literacy is associated with poor self-care in many chronic illnesses, research on self-management education of diabetic persons is scarce and efforts to develop education materials that are adapted to the level of health literacy of people. That makes it difficult for many patients to remain adherent to physicians' treatment plans, especially those who suffer from CD conditions like diabetes (Apfel & Tsouros 2013).

The National Community Pharmacists Association (NCPA) of U.S. has proposed to apply innovative patient engagement models for improving medical adherence challenges. It has been demonstrated that engaged patients are 2,57 times more likely to stay adherent with their medications (Painter et al. 2015). These models foresee the use of technology solutions, such as platforms for scheduling appointment days, sending reminders and meeting with professionals to review their current medication plan. Based on the findings, the technologies help patients to get on a schedule with refilling their prescriptions.

Traditional ways of promoting adherence like brochures or having staff make frequent reminder calls are expensive, time-consuming and ineffective. Digital engagement tools provide greater convenience and functionality at a lower cost, allowing patients to have the right information at the right time, which improves patient adherence to treatment plans and drives better outcomes (Cox 2015).

Advantages of mobile device engagement include:

- Communication with patients is easy and inexpensive, in the manner they are used to receiving consumer information
- Patients can electronically schedule their own appointments and set reminders to ensure they get the care they need.

- Relieves clinicians from having to make time-consuming reminder calls
- Patients stay better informed because they get brief messages that they are more likely to read
- Digital engagement reduces the likelihood of unnecessary appointments

Some digital engagement tools also include self-scheduling capabilities that make it easier for patients to connect with primary care physicians. Finally, when patients receive verbal instructions by their physicians, they tend to forget about half the information. A mobile engagement tool could represent a smart alternative, providing to be highly successful in ensuring patient adherence to treatment plans, which in turn produces better outcomes at a lower cost.

3.1.3 Self-Management

Another way to conceptualise patient behaviour related to diabetes management is to use terms such as “self-management,” which simply describe the behaviours patients engage in to manage their health condition.

Self-management as a term, is very common when it comes to behavioural interventions and healthful behaviours in the management of chronic disease. The positive opinion about self-management interventions is the outcome and cost of chronic illness. Integrating self-management in usual health care remains a challenge. There are at least three known barriers for this integration: (a) preparation of the system, (b) preparation of patients, and (c) payment mechanisms (Senécal, C., Nouwen, A., & White 2000).

Many improvements have been made in the treatment of diabetes in recent years. However, many patients do not achieve optimal outcomes and still experience other complications that influence their quality of life. The existing health care systems deliver more general services in acute, symptom driven care and they are not very efficient to treat chronic diseases like diabetes which needs a collaborative daily self-management plan. Considering the serious and chronic nature of diabetes, the complexity of its management, and the multiple daily self-care decisions, the self-management plan that is designed to fit patients' diabetes, should be tailored to fit patients' priorities, goals, resources, culture, and lifestyle. Moreover, research shows that effective intervention strategies should support patients to make decisions about goals, therapeutic options, and self-care behaviours (Funnell & Anderson 2004). Other studies were focused to understand the difference in knowledge, self-management behaviours and metabolic control in Diabetes Self-Management Education (DSME). The results showed that the success of DSME for

improving knowledge, behaviour and metabolic control outcomes among patients with T2DM depends on type of intervention, teaching methods, model of delivery, format, and dose (Fan & Sidani 2009). However, the vast majority of papers emphasise that a well-structured diabetes education which addresses all major aspects of diabetes self-care and the reasons for it, should be made available to all adults with diabetes. Among many of the benefits of patient education, most authors agree that the following are some of the main contributions of education for people with diabetes (Tidy 2010):

- Improving knowledge, health beliefs, and lifestyle changes
- Improving patient outcomes - e.g., weight, HbA1c, lipid levels, smoking, and psychosocial changes such as quality of life and levels of depression
- Improving levels of physical activity
- Reducing the need for, and potentially better targeting of, medication and other items such as blood testing strips

Diabetes education must be flexible enough to suit the needs of the individual - e.g., cultural, linguistic, cognitive and literacy needs. Research work has supported the findings that diabetes education focus should be on the settings in which DSME is delivered and evaluated. Among the settings considered as a primary target in which DSME training and other public health interventions delivered are: work sites, churches, senior centres, community centres, homes, extended-care facilities, and academic institutions. The efficacy of optimal DSME and training requires the patient to circumvent social and physical environments that hinder adherence to prescribed regimens. Figure 17 shows the effects of DSME on short-, intermediate- term outcomes (such as knowledge), and long-term outcomes (such as blood glucose level after fasting) (Jr et al. 2004).

Figure 17. Analytical framework showing diabetes self-management education interventions (DSME) (Jr et al. 2004).

It is already established that educational interventions improve adherence by providing information and/or skills regarding the nature of the disease, the array of diabetes self-management behaviours, and the positive and negative consequences of not adopting health recommendations. Educational interventions are provided in various forms such as: visual mediums, multimedia, computer software, or other internet sites, however, for successful implementation it is crucial to provide simple and clear messages which are tailored to the needs of the individual, and verifying that the messages have been understood (Schechter & Walker 2002). In order for the intervention to be effective, and for the results to be of significance, the messages not only need to be simple and clear, but the language and especially the level of the language, must be aimed at the patient's comprehension level. If a patient only partly understands a message, or implements what they believe the message to require of them, this could lead to poor implementation of the intervention. Local culture and socio-economic status of patients will all play a role in the effective phrasing, understanding and application of the messages.

Diabetes self-management is a key determinant of health outcomes because diabetes needs a complex array of self-care behaviours such as: taking medications, monitoring blood glucose levels or exercise. Research papers report the findings of the association between diabetes self-management and glycaemic control. These findings support the conclusion of patient self-management potential for understanding and improving glycaemic control (Lorig & H 2003). However, self-management support can be viewed in two ways: as a group of techniques and tools that

support the patient to choose healthy behaviours, and as a fundamental transformation of patient-caregiver relationship into a collaborative partnership. Self-management as supportive tool for patients to take an active role in their conditions involves two inter-related activities (Bodenheimer McGregor, K., Sharifi, C. 2005):

- Helping patients with adequate information for their chronic conditions
- Working in partnership with patients to make medical decisions and encourage them and improve self-motivation

Real self-management support goes beyond traditional knowledge-based patient education and includes collaborative decision making. Through such cooperation, physicians provide guidance for patients to achieve their goals, identify barriers, inform about plans for overcoming the barriers, and obtaining necessary resources (Coleman & Newton 2005).

The increasing influence of the internet on the daily life of people has brought a new perspective for those with various diseases. Internet-based diabetes management is also considered to have a strong potential for future health care. While this opportunity is being used for different disease management, there are some critical factors that can define its success in diabetes. The existing literature shows that the management of diabetes via the Internet is based on several integrated dimensions:

- Monitoring
- Information
- Personalisation
- Communication
- Technology

A successful diabetes management system should efficiently integrate all dimensions (Krishna & Boren 2008). A new way for better management of diabetes and chronic diseases is mobile health technology. This is considered as a new important dimension in healthcare which enables access to information, data and services to a large part of the global population. In this way mobile solutions have the capability to support more effective and qualitative diabetes care, which could be translated via patient-centred disease management (Solutions 2013). An example is the web/mobile based platform founded by the European Commission (FP7-ICT-2011-

288209) with the aim to use ICT for supporting self-management activities of diabetes patients and their treating physicians. This platform that is also available for mobile devices enables patients to upload their personal data regarding blood glucose measures, or physical activity parameters and nutrition. Moreover, through this system, patients can define goals and track their improvements during the intervention, while at the same time the physicians can provide their recommendations into the system. This integrated platform can have important implications in practice and in disease management (Mantwill et al. 2015).

Text messages are a low cost ideal platform for the delivery of diabetes self-management support. Among many solutions, a self-management support for blood glucose is considered an important platform. This system incorporates prompts around diabetes management, education lifestyle factors, and blood glucose monitoring and is also adjusted to patient preferences and characteristics. Results have shown that based on the patients satisfaction and perceptions of the usability, a tailored text message-based intervention is both acceptable and useful in supporting self-management in people with poorly controlled diabetes (Dobson et al. 2015).

Furthermore, mobile phones have the potential to assist patients with intensive insulin treatment. In order to evaluate the feasibility and acceptance of mobile phones, a software application called Diab-Memory was developed to help T1DM patients in diabetes management. The software supports patients when entering diabetes-related data with synchronisation to a remote database at the monitoring centre. The data are then processed to create the statistics for patient and professional health care via a Web portal. The testing results showed that this proposed management system was successfully accepted by patients with T1DM in their daily needs. The system is easy to use and a cost effective solution for other types of diabetes as well. Figure 18 shows a schematic representation of the system which collects and creates graphical data that are accessible to the patients via a Web portal (Dick et al. 2011).

Figure 18. Overview of the mobile phone-based diabetes self-management system (Dick et al. 2011).

Another review study showed the beneficial outcomes in behaviour change, learning, and health status of people with diabetes by using mobile phones. Most of the papers reported that educational interventions providing personalised advice and support delivered through a mobile phone can help avoid diabetes symptoms by providing timely treatment adjustments. Considering the large number of people that own mobile phones, text messaging is a new alternative that can impact the costs of diabetes treatment and provide necessary communication when combined with other methods of education and support (Schechter & Walker 2002).

Even though self-management is composed of many different components which are elaborated above, there are some essential elements that should be available in order that people with diabetes will have a minimum support for self-management. These elements are summarised below (U. K. Diabetes 2009).

- Personalised care planning
- High quality, tailored information
- Access to structured education
- Access to healthcare professionals and trained specialist advice when required
- Emotional and psychological support
- Support from peers' family, friends and carers

Personalised care planning is characterised as a process or mechanism that is centred on making consultations and sharing perspectives between the persons with diabetes and the practitioner and make joint decisions on actions needed to minimise health risk. In fact, care planning is considered as a great chance for patients to achieve personal action plans regarding diet, physical activity and diabetes management. Care planning implementation takes into account the social and health service context, as well as the way that information is managed. Figure 19 shows the elements of the care planning model for diabetes and their relationships (Graffy et al. 2009).

Figure 19. Example of personalised care planning in diabetes (Graffy et al. 2009).

Another key element for diabetes self-management is access to structured education. This is considered as an effective and cost efficient way of improving outcomes especially when they are combined with care planning, screening and medications. Structured education, in general, can help people with diabetes improve their knowledge, skills and confidence, which increases their control for their own condition and at the same time, enables effective self-management into their daily lives. However, the evidence shows that only a small percentage of people (12%) with T2DM can have access on the structured education system while only 2% of them take up the offer (Dinneen 2008).

Results support the finding that besides the glycaemic control effect on improving diabetes complications, similar results can be achieved through lifestyle and self-management changes. An example is the X-pert structured education program that was used from more than 6 weeks by healthcare professionals to increase partici-

pants' knowledge, skills and confidence to make informed decisions and self-manage their condition (Deakin 2012). This structured education programme offered knowledge on a wide range of topics to help people understand: a) health and disease, b) tablets and insulin, c) food, nutrients and digestion, d) what health results mean, e) the benefit of physical activity, f) weight management, g) the impact of blood glucose, blood pressure and blood cholesterol levels on long-term health, and h) Self-management of diabetes.

Results showed that the X-pert health's structured education program reduced the requirements for diabetes medication, improved health, individuals' quality of life and reduced the cost to the NHS. Moreover, these facts supported the conclusions that if individuals make significant lifestyle changes, they can indeed halt and even reverse the progression of the condition despite the assumption that diabetes is a progressive condition (Deakin 2012). Similar results were reported by other authors who assessed the effectiveness of a brief structured diabetes education programme based on self-efficacy, self-care and glycaemic control. It was shown that structured diabetes education programmes enhanced the diabetes knowledge and clinical outcomes in the intervention group compared with the control (Tan et al. 2011). Equally important for diabetes self-management is the right access to healthcare professional and trained specialist advice when required. It is always recommended that hospitals should provide a diabetes specialist team to support patients with diabetes and the staff caring for them. Input from the diabetes specialist team is essential to ensure patients with diabetes are managed safely and effectively during their hospital stay. Indeed, the specialist advice and support is based on several activities such as (Joint British Diabetes Societies for Inpatient Care Group 2012):

- Developing and implementing local self-management policies;
- Providing staff education in the use of self-management policies to ensure that the staff understands when patients are safe to self-manage diabetes;
- Pre-planning for elective inpatients;
- Providing support where difficulties arise in deciding whether patients are able to self-manage;
- Investigating untoward incidents that arise as a result of self-management;
- Auditing the self-management process.

It is important to mention that most diabetes care is done by primary care providers. Only 20% of patients have been visited by an endocrinologist, and there are not nearly enough endocrinologists to handle the ever-increasing number of people with diabetes. It means that the main work in diabetes management is based on the advice of generalists. These facts are alarming since diabetes management matters not just blood glucose control, but include many other parameters that need a professional explanation.

Diabetes management depends strongly on patient self-care, therefore, people with diabetes must know a great deal about their own condition and its management to achieve their management goals (Saudek 2002).

The access to healthcare professionals and trained specialists includes the attending nurses. In fact, nurses tend to spend significant time with patients, provide necessary education, listen to patient's needs and know them better than physicians. These facts show that nurses should better understand psychosocial issues in order to help patients to take responsibility for their care. The access to such professional personnel enhances the self-management, because qualified nurses teach medication management, have a higher level of involvement in medication prescribing, and are more willing to take on additional responsibilities than generalist nurses (Siminerio et al. 2007). Their results emphasise that people with diabetes want and need access to emotional and psychological support which is not available all time. In fact, emotional and psychological needs are recognised as an important factor to help diabetic patients for self-management and long term physical health. This support is needed in all contexts such as: interpersonal relationships, family life, employment and education. The intensity of such needs depends on various conditions and can vary from intermittent mild concern to persistent high levels of distress that may result in unpleasant physiological symptoms, low mood, loss of motivation, eating disturbances and inadequate self-care. However, it is important to mention that emotional and psychological care are considered in health care systems as an integral part of all diabetes care pathways, regardless of organisational boundaries. These needs are very complex for both diabetics and those who care for them. They are described by using a pyramid model (Figure 20) which shows their diversity and relationship between prevalence and severity. Emotional and psychological needs at every level are likely to make the core of diabetes care harder to achieve (National Health Service 2010).

Figure 20. Pyramid model describing the prevalence of emotional and psychological problems in relation to their severity (National Health Service 2010).

Positive changes on quality of life and hematologic measures which predict the long-term health and well-being in patients with diabetes were observed in a pilot study which used the emotional self-regulation programme. The results showed that such interventions can reduce stress, improve psychological health, enhance quality of life and may help improve glycaemic control in individuals with diabetes (McCraty et al. 2000).

Besides, the parameters mentioned above it is crucial for diabetes patients to have an adequate social network and support in their self-management challenges. This support is considered valuable and results show that is very beneficial for patients. The social support includes family relatives, peers, friends, neighbours, colleagues, fellow patients, or even penfriends, as well as social networking on the Internet. Even though there is a list of influential factors, the treating physicians should consider using a personalised approach, where the focus is on tailoring treatments as closely as possible to patients' needs.

The treatment should consider more carefully the social support network of a diabetic and the levels of influence (Figure 21) that it has on patients' self-care. Moreover, the personalised therapy should be designed by taking into account the individual's health literacy, demographic factors, and cultural values for disease management (Kadirvelu et al. 2012).

Figure 21. Levels of influence of social support networks in diabetes self-care (Kadirvelu et al. 2012).

The self-management task such as glucose testing, insulin injection, diabetes meal planning, checking feet, and exercise, often take place in social settings, and can alter family and social routines, therefore the support from families and friends is crucial to overcome social barriers and executing complex self-management behaviour. Moreover, family and friends can offer practical and emotional assistance which is considered important on diabetes self-management behaviour. These conclusions are supported by various studies which found a positive correlation between family-and-friend support and diet, exercise, foot care, testing for sugar, and compliance with medication. (Miller & DiMatteo 2013). The evidence shows that involvement of family members in psychosocial support and intervention might be very beneficial, however, many scientists agree that the roles of such interventions are neglected especially in T2DM.

Family characteristics and cultural beliefs also play influential role in diabetes self-management behaviour. However, it has been shown that despite such variations in beliefs and practices the support offered by family and friends of different cultures have positive influences on diabetes self-management. It is recommended that clinicians should play a more active role and potentiate the benefits of support from family and friends and take into consideration the barriers to self-care especially in younger patients.

The role of cultural variations needs more attention and acceptance, especially in countries with different cultures and races. Other important issues to consider are

the differences in health care systems and the consequent differing degrees of access to health care providers. The economic conditions and the gap between rich and poor in developing countries, as well as literacy levels, might also play an important role (Vaccaro et al. 2014). Along with family and friends' influence, age, sex and marital status are shown to have overlapping influences on diabetes self-management. For example, women in general exhibit better self-care behaviour, are more open to discuss their personal problems with others compared with men. On the other hand, it was reported often that men are more likely to have support from family members in various aspects of self-care. Other initiatives aim at using also the peer support to assist in daily management and act as a link to clinical care. The research evidence shows that people with diabetes can help each other in various aspects, like sharing knowledge and experience that others, including many healthcare professionals, cannot understand. Peer-to-peer interventions are being widely used and are in demand by patients, and appear to be of quantitative benefit in primary prevention (Heisler M. 2007). Moreover, it has also been demonstrated that peer support can offer emotional, social, and practical assistance to patients whom can be critical to manage their conditions and stay healthy. This type of support can work as a synergy to enhance other health care services that enables people to follow management plans in daily life, stay motivated and at the same time get advice from health care providers for their needs. It means that peer support can work as a constant link for people living with a chronic disease or condition, so that there is sharing of knowledge and experience in a very unique way that other supporting methods cannot provide (Wientjens 2008).

3.1.4 Health communication

Based on the definition of "Communication as a multi-way process" of (Corcoran 2007), the patient- professional model of communication can be conceptualised in five steps:

1. Sender
2. Message
3. Receiver
4. Complete understanding by that receiver
5. Feedback to the communicator.

These last two steps are very relevant in health communication, as they imply the multi-way communication between patient and professional. The communication of these two factors consists of a cyclic process involving a series of actions. An idea

of how this approach can be modelled is represented is shown in Figure 22. As it can be seen, communication is circular and includes five stages:

1. Professional define the Messages;
2. Messages are sent to Patient
3. Patient receive and interpret the Messages;
4. The patient's Understanding generates a reaction or Feedback;
5. Messages' Feedbacks are sent back to professional

Figure 22. Communication as a multi-way process applied to health communication (Corcoran 2007).

The way a message is expressed is highly influential on an individual's reaction, which can be positive or negative. Also the usage of complex medical technology and abbreviating key terms can confuse the understanding of a message and limit the target audience, while using repetition has been positively found to influence communication. "Behavioural Change Theories and Models" in health promotion usually seek to include key elements important to behaviour and decision-making processes. In health promotion and health education, models are often borrowed from areas of social psychology or health communication and applied to health contexts.

3.2 Behavioural Change and Persuasive Theories applied to Diabetes

The theories of change, also named behavioural change theories, support interventions by describing how behaviours develop and change over time. These models are designed to help understanding individuals' behaviour and identify the underlying factors that influence it. Psychosocial factors can help to explain how and why some individuals are able to achieve lasting changes to their health behaviours and adhere to their prescribed medical treatments.

Possible predictors of an individual's success at implementing a behaviour change regimen or adhering to medical advice include: (1) factors related to the regimen itself, such as complexity, burden on lifestyle, side effects, and immediacy of symptom relief; (2) factors related to the individual, such as mental health, level of health literacy, personality, coping style, self-efficacy, outcome expectancies, personal motivation, and level of cognitive impairment; (3) demographic characteristics of the individual, such as their gender and socio-economic status; and (4) interpersonal factors, such as the availability of social support, the level of family conflict, and the patient's communication and relationship with the health care provider.

All of these predictors of behaviour change may offer direction and avenues for improvement, so that health care professionals can guide and support their patients in achieving the goals of health behaviour change (Kristin A. Riekert, Judith K. Ockene 2014).

One of the major problems recognised in diabetes is the non-adherence to self-management regimens. This problem is not only limited to adherence with medications, but includes lifestyle changes (e.g. diet and exercise) and blood glucose monitoring as well. Poor adherence to medications includes other undesirable practices such as failing to start treatment, failing to implement treatment as prescribed. Other consequences of failing include missed doses, miss-timed doses (if not taken at the time prescribed) or under/overdosing. Based on such evidence it is well recognised that people with diabetes must be adherent to self-management regimens in order to have beneficial health care effects and appropriate interventions (NíMhurchadha, S., & Sayers 2014). There are a large number of behaviour theories and models to address particular behaviours. However, there are different uses and limits of these theories and models in behaviour change.

While behaviour models help people understand specific behaviours, by highlighting the underlying factors which influence them, behaviour theories show mainly

how the behaviours change over the time and can be changed. Based on the literature that covers behavioural models and theories, human behaviours are complex, arising from different psychological factors, and from societal and contextual influences. Indeed, helping a person to their existing behaviour needs:

1. Individually tailored intervention
2. Support for developing motivation to make changes
3. Goal setting and action planning as well as continuous support and encouragement in order to maintain the change.

Figure 23 shows a model that has the main processes involved in behaviour change (IMAGE Toolkit working group 2010).

Figure 23. A process model for supporting lifestyle behaviour change (IMAGE Toolkit working group 2010).

Considering this diversity of influential factors, changing the behaviour is challenging and potential models should address a number of factors at once with high flexibility. As the number of theories and models to promote treatment adherence is proliferating, research highlights some of the most effective theories and models for improving long term adherence.

As of today, more than twenty different behavioural change theories, applied to CD self-management have been designed. Below is the summary of some relevant theories and models (Kristin A. Riekert, Judith K. Ockene 2014).

- Health Belief Model (HBM)
- Social-cognitive theory (SCT)

- Theory of Reasoned action (TRA) and Theory of Planned Behaviour (TPB)
- Protection Motivation Theory (PMT)
- Self Determination Theory (SDT)
- Elaboration Likelihood Model (ELM)
- Behavioural Learning Theory (BLT)
- Goal-Setting Motivation Theory (GST)
- Transtheoretical Model (TTM)

An example of application of such models in diabetes is the use of HBM for diabetes management. This model has many applications explaining self-care activities and has the main focus on behaviour related activities to the prevention of diseases. The role of HBM is more evident when individuals take action to prevent, control, or treat a health problem if they perceive the problem to be severe in nature (Adejoh 2014).

The HBM has six constructs: perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self- efficacy and cues to action (Figure 24).

Figure 24. Flow diagram of the health belief model showing its six constructs (Adejoh 2014).

Many scientific researchers have concluded that HBM constructs may initiate the changes and improve the behaviour of patients. Results from these studies confirm that increasing the mean grade scores of knowledge and constructs of HBM of patients, resulted in better foot care by patients themselves. Moreover, HBM was proven to be reliable and with potential for establishing educational programmes for individuals and communities. This evidence suggests that this type of model is effective to prevent different complications in diabetes (Sharifirad et al. 2007).

Improving diabetes adherence is a challenge that requires a motivated client and a skilled health care provider. Another model proposed by scientists that can provide

valuable results and achieve success in diabetes management is the transtheoretical model (TTM). The main tenet of the model is “that people are in continuum of readiness to change the behaviour and there are potential movements forward and backward throughout the cycle”. According to the theory there are some stages of change like: pre-contemplation, contemplation, preparation, action and maintenance. In many cases results have shown that this model is beneficial for motivating clients with diabetes to adhere to recommendations (Laura Hill, Lori W. Turner 2008). It is always important to know the stage of change people are in at the beginning of treatment in order to use the TTM and to evaluate possible changes and improvements. In this way many healthy behaviours can be promoted which can finally reduce the risks associated with diabetes (Andres, A., Gomez, J., & Saldana 2008). Figure 25 shows basic components of a TTM which is applied in a wide range of problems including diabetes (Sledd 2014).

Figure 25. Transtheoretical Model showing the stages that a person goes through on the path to change (Sledd 2014)

Recent results have shown the efficacy and application of several behaviour models in medication adherence intervention of people with diabetes. Using data from the motivation and behavioural skills allows assessing the degree to which change in these determinants, leads to changes in medication adherence behaviour. An example is the Information Motivation Behavioural skills (IMB) model used to conceptualise the determinants of diabetes medication adherence among a low-income, diverse sample of adults with T2DM.

Results have shown that adherence information and motivation were associated with adherence behavioural skills, which are known to be associated with diabetes medication adherence. In all test results the IMB model was useful to explain the

medication adherence behaviour. It was concluded that such might include strategies to ensure that patients possess appropriate knowledge about their medication regimen and skills to obtain adherence information when needed. Figure 26 shows an example of the Information Motivation Behavioural skills (IMB) model used in diabetes medication adherence (Mayberry & Osborn 2014).

Figure 26. Information Motivation Behavioural skills (IMB) model of diabetes medication adherence showing the effects between constructs in diabetes adherence and health outcomes (Mayberry & Osborn 2014).

The IMB skills model was assessed as a short-term, low cost behaviour change framework for patients with T2DM patients. It showed that the model can improve self-care behaviour based on the evidence that the total self-care and the self-care of diet and exercise had been increased significantly in the experimental group. The behaviour change and the weight loss observed were characterised by a significant decrease of HbA1C in the experimental group. Moreover, the model also improved, to some degree, the self-care of glucose control, and foot care. All data supported the conclusion that the IMB model can be an effective method for improving the self-care behaviours in patients suffering from T2DM patients (Gavgani et al. 2010).

Mobile phone apps have many features that can support patients and health care professionals to improve their medication taking behaviour. Considering the increase of the number of people using mobile phones, medication adherence-oriented apps (adherence apps) can potentially organise all of the user's medication-specific information to create a more efficient process to educate the individual about their disease or care. The number of apps dedicated to improving adherence is increasing and more advanced features are being introduced. Some examples include reminders that can be set for consumption and refills, doses that can be logged, data logs that can be accessed by patients or uploaded to care providers,

and medication information. Moreover, recent efforts are focused on integration of mobile phone with health-monitoring devices that transmit the output data directly to patients or professionals. Considering the cost effectiveness, accessibility and scalability of such adherence apps, they could be considered a possible strategy for caregivers to recommend to non-adherent patients and to incorporate into their practice. With the aim to improve the medication adherence a mobile app was developed, whose objective is to remind the patients of their dosage timings through alarm ringing system was developed. While different apps are available with diverse features, this system is more focused on some specific needs and requirements. It has an alarm that can be used for multiple medicines and timings including date, time and medicine description. The alarm is usually sent to patients through email or text message and enables the users to have access on different articles related to medical fields and health care tips with easy navigation (Dayer et al. 2013).

3.2.1 Persuasive Technology

Persuasion is part and parcel of human interaction. Persuasive efforts abound in a continuous attempt to influence individuals' attitudes and behaviours, trying to convincing to spend money on one product rather than another, to stop smoking or to exercise more. eHealth technology is playing a significant role in facilitating the delivery of persuasive messages to and it is starting to integrate especially powerful tools in altering and adjusting the pattern of interaction based on the characteristics or actions of the persuaded party, such as the user's inputs, needs, and context. This realisation has led to the investigation of persuasive technology, defined as a class of technologies that are intentionally designed to change a person's attitude or behaviour (Fogg 2003). Of course it is important to persuade towards a voluntary change of behaviour, and not through intents (Ijsselstein et al. 2006).

Persuasive technology has great beneficial potential if applied to improve human well-being. Mobile health application, based on persuasive gamification methodologies and incorporating physiological data, have been shown to encourage a more active lifestyle (Lin et al. 2011).

Persuasive health information provision plays an important role in determine whether a patient engage in recommended health behaviours and whether the behaviours have positive outcomes. When interacting with patients, health systems should aim influencing the patient opinions and attitudes and consequently change the behaviour. Edwards and Hugman (Edwards & Hugman 1997) identified six core issues that need to be taken into account in health persuasion communication:

1. Purpose of message

2. State of mind of the intended recipient, including cognitive abilities and emotional state
3. General context in which the message will be received
4. Medium of communication to be used
5. Feedback mechanisms to assess the effects of the message
6. Monitoring and evaluation

In most cases, healthcare systems need to consider many of the above-mentioned indicators when planning to communicate with a patient.

Although current research that aims at improvements in health related behaviour is valuable to encourage health behaviour change, the current interventions tailored to persuasion on care plans' adherence could be more effective. In particular, through the identification of specific pattern of a patient that might condition on responding adversely to a persuasive intervention, higher intervention adherence could be achieved by the adaptation of persuasion strategies. The difficult task of achieving behavioural compliance might be accomplished when persuasive messages are combined with other intervention strategies, aimed at decreasing perceived effort and increasing anticipated rewards (Hutchison & Mitchell 2010).

3.3 mHealth and Behavioural Change

Rapid developments in technology and increasing computerised health behaviour interventions in the last decade have promoted the migration of computerised health behaviour interventions from prototype stand-alone software to robust, scalable, interactive, and tailored web-based programmes. In fact, while at the beginning these theories were mainly treated from psychologists and physicians through individual session on healthy habits guidelines, in the last decade they have often been applied in ICT, in particular in mHealth technologies.

As a result, web-based health behaviour interventions are considered an effective method for improving the delivery of health behaviour interventions in a cost-effective manner. These advances offer the chance to develop the dynamic feedback system theories of health behaviour which can be developed using longitudinal data from mobile devices and other control systems engineering models. However, it is well known that mobile phone interventions are providing several advantages and capacities to interact with the individuals with much greater frequency in the

context of behaviour compared to internet interventions based on desktop and laptop computers.

While the health behaviour theories and models such as the HBM, the TPB, the SCT, the TTM and the SDT have served as the basis for many web and desktop/laptop computer interventions, it is expected that they will be more frequently applied through mobile phone technologies in the future (Riley et al. 2011). Despite the wide application of behavioural models, their application through mobile phone-based interventions is lacking. Results obtained from the African-American population showed the positive effects of the text message-based programmes and mobile phone-based diabetes programme on self-management through multiple behavioural constructs including health beliefs, self-efficacy, and social support (Nundy et al. 2013).

Studies have found that periodic prompts and reminders are an effective method to encourage and reinforce healthy behaviours (Fry & Neff 2009). Increased communication reinforcement, created by text messaging, can improve the likelihood of remembering the changes that one should be making. A study conducted by (Pena-Robichaux et al. 2010) illustrates that the use of Daily text messages, a simple and inexpensive technology, may be effective as a reminder aid and educational tool in young patients with atopic dermatitis.

There are several approaches available to support the monitoring, management, and treatment of patients with diabetes mellitus. One example is SMARTDIAB platform designed by combining state-of-the-art approaches in the fields of database (DB) technologies, communications, simulation algorithms, and data mining. The patient management unit of the platform can be accessed through the internet by using devices with direct internet access of mobile phones. The device is able to collect the patient's information and transmit it to the management unit which has a diabetes data management system. The decision support system then provides the necessary risk assessment which can be accessed from both medical personnel and patients (Mougiakakou et al. 2010). A similar model was developed and used by a mobile phone to support self-management in patients with T2DM. The approach is based on mobile phone which enabled access to daily web based diaries where participants provided their eating behaviour, medication taking, physical activities and emotions three times daily using the mobile device. Based on such data, the therapist uses the information to create appropriate feedback. Results showed that the developed smartphone application is a promising tool for supporting patients with T2DM to make important life style changes (Nes et al. 2012). Mobile health technologies and smart home based software can also assist in the behavioural monitoring of diabetes patients. The smart home based software developed

uses the patient information to increase the effectivity of diabetes self-management education and at the same time providing more information for health care professionals. Figure 27 shows an example of a software architecture that provides flexible, interoperable, plug-and-play integration of health monitoring components from smart home data collection through data analysis and recommendations. Indeed, results have shown that such architecture can support behavioural monitoring for diabetes patients beyond the information that can be accessed by self-reports or collected in a medical practitioner's office. It was concluded that using these innovative technologies a significant improvement can be provided for people living with diabetes and the health care costs associated with treating the disease can be reduced (Helal et al. 2009).

Figure 27. Health platform architecture developed and its layers (Helal et al. 2009).

Furthermore, other studies have shown that more directive messaging is important to help patients effectively manage their diabetes. In an attempt to test the role of computer-generated, tailored feedback on chronic diseases management and T2DM in particular, 203 adults with T2DM were randomly assigned to groups receiving efficacy (positive) messages (68), risk (negative) messages (67), or delayed treatment control group (68). It was concluded that interventions delivered before the patient's visit provided more benefits in terms of discussing the message at the clinical appointment. Moreover, patients have benefits from directive feedback by preparing specific questions to ask their physician regarding their needs than can lead to improved care (Adams et al. 2009).

Using mobile phone text messaging and e-mail reminders is also demonstrated to be a well-accepted and cost efficient modality for engaging youth and young adults in the management of diabetes. This approach was tested in forty insulin-treated adolescents and young adults with diabetes which received electronic reminders to

check their blood glucose levels via cell phone text messaging and some other e-mail reminders for 3-months. Even though maintaining the interest for a long period of time was a challenge, results supported the finding that cell phone text messaging is a reliable and effective option in adolescents and young adults with diabetes (Hanauer et al. 2009). The text messaging has more advantages because other services like web page based communication requires devices that are not available to all patients at the required time. This system has been used in other similar problems and now people with diabetes have started to use this advantage as well.

For people with diabetes is very important to overcome the limitation of stationary computer systems and deliver the data on demand. Therefore, this service is considered to be more of an option that does not replace the patient-physician system, but supports the self-management to take control of their diabetes. For example, the short message service (SMS) usage between the clinic visits was used and the effect in glycaemic control was evaluated. The test was used in an interventional group as well as in control group. The intervention group had two mobile numbers for SMS support and results showed a significantly greater reduction in HbA1c ($p=0,001$), 1,16% lower compared with controls. It was concluded a good acceptance of the service and effectiveness in lowering the levels of HbA1c in an interventional group (Hussein et al. 2011). A similar study confirms that text messaging improved the HbA1c level in the intervention group compared with control. The conclusion demonstrated the potential of the messaging system and the promising effects on glycaemic control. Studied individuals described the messages to be easy to use, helpful in remembering to complete tasks and increasing their motivation (Mulvaney et al. 2012). This methodology was further applied to understand the potential on improving laboratory test levels and Knowledge, Attitude, Practice (KAP) and Self Efficacy (SE) of patients with T2DM. These results showed that the experimental group that received 4 messages weekly consisting of diet, exercise, and medication taking, improved significantly in measured parameters. The results provided after intervention showed the effectiveness of SMS phone messaging intervention in the management of T2DM (Goodarzi et al. 2012).

Acceptance and interest of patients for using text messaging to control and improve their diabetes conditions, different services are proposed and established. While some of the examples mentioned above showed the application of such systems on improving various parameters at the same time, others have been focused only on blood glucose. For example, mobile phone text messaging was used to provide blood sugar measurement prompts and appointment reminders in adults with dia-

betes. The data about blood sugar were requested 3 times per week and the reminders were sent 7, 3, and 1 day(s) before each scheduled appointment. Results confirmed acceptance of the process and the financial costs associated with text messaging were perceived by participants to be negligible (Fischer et al. 2012).

Several examples provided showed that text messaging and SMS, and other mobile applications, offer the chance for better communication between standard office visits and thereby complement traditional clinic-based models of care. In almost all examples of the mobile phone projects, the results confirmed acceptance as well as improved disease control in patients with diabetes who received a mobile coaching programme compared to usual care. However, there are limitations reported and often it was concluded that mobile health interventions may not be appropriate for different real-world health systems. Little attention was paid about how to create mobile health interventions that integrates and improves the existing systems of chronic care. In an attempt to answer these challenges, a new system was developed which used the input data from patients, providers, and health plan administrators. The pilot study demonstrated that the programme modified participants' beliefs about their diabetes, increased their confidence in self-management, and most surprisingly, provided social support.

Results provided a new approach to develop a behavioural model that can describe how mobile phone-based interventions affect self-management. Figure 28 shows a schematic representation of a text message-based chronic care programme (Nundy et al. 2012).

Figure 28. Conceptual representation of the text message-based chronic care program. 1) Health plan care managers enrol eligible member with T1DM or T2DM over the phone. 2) Patient receives self-management support via automated text messages and respond to queries via text message. 3) Patient's responses help to dynamically tailor content. 4) The CareSmarts system collects patient data from the text message responses and 5) alerts the care manager when exceptions require attention. 6) Using protocols, the care manager provides telephone-based support to the patient and 7) co-ordinates care with the provider. 8) The provider follows up with the patient for any necessary care, (Nundy et al. 2012).

In some cases, the mobile phones were used with integrated software that could help improve their conditions. Comparing results between two groups of patients (patients that received mobile phones with diabetes management software and control group) after one year, it was concluded that patients with the mobile management system showed better results: the A1C levels decreased for 1,9 percentage points, compared with a 0,7 percentage-point decrease among patients that did not use the mobile phone system (Quinn et al. 2011).

Despite the fact that the number of approaches that use mobile phones for better diabetes treatment, there is no standard measure specifically designed to assess usability of a mobile-phone-based self-management tool for diabetes. Scientists have contributed towards better understanding the factors that influence the usage of a mobile self-management applications over time by investigating each participant's engagement.

Currently there are a number of different mHealth commercial solutions that can support patients with chronic diseases in general and diabetes in particular. For example, a personal analytical platform called Tictrac was developed with the aim to enable people to control their data, display them in a dashboard and use the information to assist in making better life decisions. Indeed, its features allowed people to make comparisons across the data and understand more about themselves (Solon 2012). A new way to support people on making better decisions is considered a computing platform which is focused on human data analytics. The data are collected based on a wristband that monitors physiological signals which are then analysed on a secured cloud platform (Garbarino, Maurizio 2014).

An intervention for T1DM considered a text messaging support called "Sweet Talk". The platform was designed to support patients between clinic visits using text messages sent to a mobile phone. The message content was recorded and analysed using different quantitative and qualitative methods. The information gathered from patients was categorised into 8 main categories: blood glucose readings, diabetes questions, diabetes information, personal health administration, social messages, technical messages, message errors, and message responses. The Sweet Talk system was considered as a trusted medium for communicating with care providers, and could be readily adapted to suit other chronic disease models and age groups (Franklin, V. L., Greene, A., Waller, A., Greene, S. A., & Pagliari 2008). Figure 29 shows an example of text messaging Sweet Talk system used in young people with diabetes.

Figure 29. "Sweet Talk" system designed to support patients between clinic visits using text messages (Franklin, V. L., Greene, A., Waller, A., Greene, S. A., & Pagliari 2008).

Recently a new innovative app (EndoGoddess) was introduced which is designed to promote sustainable behaviour change of people with diabetes by influencing patients' decision making processes using a rewards system. This app improves the communication between patients and doctors and in this way lowers the health risks associated with hospitalisations needed when diabetes care management decreased. The app is based on some basic features implemented through 4 steps: (EndoGoddess 2014).

- Patient records their glucose measurements four times a day
- In return, the patient earns rewards
- The professional can review, record, and adjust their care plan as needed
- Patient Goes to iTunes and downloads rewards ranging from songs to glucose strips and gym memberships and more

Some other types of apps are designed only to support the optimistic thinking of patients. These are known as "optimism mental health apps" and they help people to understand the factors that might influence their mental health. The apps act as a springboard to detect patterns in your health and create strategies to better manage depression and mental health conditions. The application is based on some key features such as; develop and monitor strategies, that help the user remaining in

good health, detect factors that affect the health and document new wellness plans that details strategies and appropriate steps in the event of illness (Optimism 2010). Another promising app that is supporting better communication between the patients and doctors is “Discover”. Patients can use this app on their mobile devices and control their medication, activities, glucose and blood pressure. At the same time health care professionals use the app to review the patient’s data and needs, and design the best treatment method for them (Proteus 2014). The so called “my quest” mobile app works in a similar way, but has some more integrated services. This app helps patients by delivering the relevant medical treatment information through tablet and mobile phone. It has a wide range of solutions integrated that provides access to patient’s information wherever they go. Some of the features include Receiving laboratory data results, receiving medical reminders, monitor weight and body mass levels (Quest Diagnostics Incorporated 2015)

Some mobile applications and software are designed to support patients in their medical adherence. For example, a personal caregiver is considered a useful tool for better health. The aim is to help people, including parents and children, providers and caregivers to manage medication adherence and improve their overall health more easily. The platform is designed to help more than one person to avoid missed doses and avoid gaps between refills (MEDIC8 MANAGER LLC 2011). New apps are constantly improving their features and connecting to science in order to cover more needs and challenges of the patients. “TactioRPM” is a science-based mobile app which is connected to health devices and monitors a wide range of parameters such as: blood glucose, A1C, weight loss, physical activity, nutrition, medication plan, education and engagement. It is a rare solution that helps health care professionals connect with their patients and understand a wide range of parameters at the same time. This allow users maintaining adequate glycaemic control and decreasing the chronic complications associated with uncontrolled diabetes. It is designed to be used in all types of diabetes. Figure 30 shows an example of the TactioRPM mobile app that is used on the T1DM. The colours represent different criteria depending on age and time of the day. When connected to the health device, it provides automatic blood glucose, insulin adjustments, wellness tracking, critical state messages, nutrition and medication plans. In the case of gestational diabetes, it provides educational resources and science-based health coaching (Coutu-Nadeau 2014).

Figure 30. An example of the TactioRPM app used in patients with type 1 diabetes (Coutu-Nadeau 2014).

Physical activity is one of the key factors for preventing diabetes and promoting good health. Furthermore, physical activity is very important in diabetes management and supports the overall mental and physical health of patients with chronic disease. However, monitoring the physical activity and sleep, without any objective measurement is very difficult. A new device called “SenseWear Armband” system works as a versatile monitor which collects and analyses the information about patients in a free-living environment, allowing them to go about their normal daily activities. The output data used by patients includes energy expenditure, Metabolic Equivalent of Task (MET) levels, number of steps and total distance, sleep duration and efficiency, physical activity levels and duration (BodyMedia 2013).

Recent technologies also aim to facilitate the interface between a computer and the human body. One innovative technology of this type is called “ZYT0”, which develops the software and integrated hardware products that are specifically focused to provide information about personal health and wellness decisions. Using scan technology, the data are gathered through a bio-survey, which includes both the computer generated signatures called virtual stimuli and the body’s galvanic skin response which is well developed for monitoring stress responses. This monitoring system is able to correlate the responses to specific virtual stressors, enable health professionals to focus on specific areas where diagnostic testing should be

performed and clinical therapy should be applied. This technology is proven to support the clinicians for better decisions and achieve better clinical outcomes (ZYT0 Corp 2015).

Future trends show that the investment on the patient's adherence mobile apps is going to increase in the coming years. Recent results showed that US pharmaceutical companies' patient adherence budget allocations have increased from \$400,000 in 2009 to \$1,5 million in 2012. Despite the large number of apps available, nearly 40% of pharma marketers agree that patient adherence activities involving mobile "apps" will increase over the next five years. Currently it is estimated that companies are spending 11% of their budget for developing mobile apps. The main focus is dedicated to simply calling/texting service through mobile phones, to remind patients to take their medications (PharmaGuy 2012). Based on the current investments, it is expected that around 33% of pharma's adherence budget will be dedicated to new mobile apps and around 25% of the investment will be simply for reminder text messaging services. Figure 31 shows some of the current spending of companies in adherence mobile apps.

Patient Outreach Activities Most Likely to Increase in the Next Five Years

Figure 31. Market trends on patient's adherence mobile apps (PharmaGuy 2012).

Above mentioned evidence shows the efficiency of mobile health systems to improve the self-management of various chronic diseases and enhance the compliance to the medical prescription, supporting patients to adopt healthy life styles and promoting empowerment. However, the existing literature also potentiates the challenges following the implementation of such systems.

3.4 Conclusions

There are many evidences supporting the beneficial clinical impacts of improved patient adherence and engagement to prevent the consequences and complications derived from diabetes. Taking with a proper care plan's adherence in diabetes must foresee a multi-method care plan approach that enclose many behavioural changes in nutrition, medication and physical exercises and lifestyle habits. Barriers to adherence are: complex treatment regimens, confusing information provided by the health care provider, socioeconomic issues, psychological well-being and personal beliefs. Behavioural change theories and persuasive approaches can help supporting the adherence success and can enable a more effective self-management of diabetes care.

Health behaviour interventions based on mHealth solutions have been shown to be effective way to engage diabetic patients in the desired behaviours change for improving the self-care management and the adherence to a care plan.

Chapter 4

Methods and Materials

This chapter describes the methods and materials adopted for addressing the objectives of this research work for answering the proposed research questions. The theories and methods used to formalise the EBF are based on behavioural theories. Mobile technology has been used for applying the framework and tests it on real users. After the models and systems have been implemented, it has been necessary to validate them from a scientific point of view. For the EBF definition, deployment, implementation and validation, different materials and methods known in literature have been applied.

4.1 Methods

The methods used to formalise the design, the implementation and the evaluation of the technological framework are based on four main phases. The first phase is dedicated to justify the definition of a method for measuring the treatment adherence. Successively, a method for defining the principles with which the technological framework is based on are described. Then, development methodologies based on user centred design, use cases and Rational Unified Process are adopted for the implementation of the framework into a mobile device. Finally, a set of surveys were adopted and an ad-hoc survey was defined to collect the data for the technological framework evaluation.

Figure 32 shows the diagram of the adopted methods to demonstrate each of the defined hypotheses of the research work.

Figure 32. Methodology scheme

4.1.1 Assessment of care plan's adherence

The measurement of adherence to a care plan is based on the definition of the WHO (Sabaté 2003): according to this definition, adherence depends on different components of a person's behaviour that converge in determine its quality of life. These indicators can be segmented in five main dimensions:

- The quality the diet
- The manner of checking physiological data
- The observance on drug intakes
- The performance of regular physical activity
- The involvement in education programmes

For each indicator, one or more formulae were defined for estimating:

- The willingness of the patient in follow adequately the treatment recommendations coming from his/her health care provider.
- The engagement of patient in use of a personal health record for introducing his/her treatment inputs.

While the usage equations are determined from the analysis of the user interaction with the system, compared with the recommended use, the treatment equations depend on the analysis of the quality of data entry. The correlation of the data coming from the Treatment Adherence's and the Usage Adherence's formulae contribute to give a projection of the quality of the patient care plan.

4.1.2 Methods for the Technological Framework Design

4.1.2.1 Behavioural Change Theories applied to the Engagement Behavioural Framework

The behavioural change domain was explored to define the framework that this research work is based on. Corresponding methods and techniques, applied to chronic disease conditions, have been largely employed from more than 40 years. As discussed in Chapter 3, the theories attempt to identify effective approaches and strategies that motivate change and sustain newly-adopted healthy behaviours. These theories cite environmental, personal, and behavioural characteristics as the major factors in behavioural determination. The following are descriptions of the theories that have been applied to the framework.

Transtheoretical Model

TTM focuses on both enhancing motivations in those not ready to optimally self-manage and changing behaviour and maintaining behaviour change for those who are motivated. Its application in diabetes care was first introduced in 1993 (Ruggiero 1993). The model consists of three core constructs ('stages', 'processes' and 'levels of change'), with the 'stage of change' describing the status of the person undergoing the change process. The stages form a continuum, and the person may move through the stages in a bi-directional manner. In order to help patients progress to the next stage, health care providers should identify the current stage and tailor their counselling strategies individually. TTM postulates that people at different stages have different needs for counselling:

1. 'Pre-contemplation' (a healthier lifestyle is not yet considered) and
2. 'Contemplation' (thinking about behavioural change): at these stages, the need is for cognitive approaches that will increase the motivation for engaging in change.
3. 'Preparation' (intending to change behaviours, with no effective action): here the need is for behavioural-skills training.
4. 'Action' (modifying one's behaviours): the need at this stage is for specific interventions and concrete guidelines.

5. 'Maintenance' (stabilising change and avoiding relapse): the need is for assistance in preventing relapse and in consolidating gains.

In order to apply the model to diabetes management, researchers recommend categorising patients into each of the stages of change (Uggiero & Reese 2003). In addition to assessing the stage of change, readiness to change can also be assessed at the beginning and end of an intervention for improvement of a specific behaviour.

Goal-Setting Theory of Motivation

The GST emphasises the important relationship between goals and performance. Research supports predictions that the most effective performance seems to result when goals are specific and challenging, when they are used to evaluate performance and linked to feedback on results, and create commitment and acceptance. The motivational impact of goals may be affected by moderators such as ability and self-efficacy. Deadlines improve the effectiveness of goals. A learning goal orientation leads to higher performance than a performance goal orientation, and group goal-setting is as important as individual goal-setting. Goal setting is a widely used behaviour change tool in diabetes education and training. As demonstrated (Miller & Bauman 2014), when used effectively, goal-setting can increase satisfaction, self-efficacy, and commitment to even more ambitious life pursuits. The employment of the GST in diabetes is represented as a closed loop among the planning conversation between clinical professional and patients, the setting of the goal and the patient's feedback and monitoring, as shown in Figure 33.

Figure 33. Goal-Setting Cycle

Guidelines from Effective Health Communication (EHC)

Health communication provision plays an important key role in determining whether a patient engages in recommended health behaviours. Communication

design paradigms will lead the definition of the messages the user receives, by following EHC strategies. In particular for advices related to education and medical tips, messages were defined following message communication guidelines from Intel Digital Group (Intel Digital Health Group 2010). The health communication principles applied to the messages are based on ten rules:

1. **Remind patient of who they want to be:** remind a patient on which goal they are trying to reach showing their healthcare goal every day.
2. **Applying social influence:** compare the patient to a peer group who practices the desired behaviour.
3. **Showing people what they could lose:** messages that leverage to the fear of loss have great effect on user persuasion.
4. **Link short term efforts with long term gains:** stress the importance on persisting in the treatment adherence for a bigger reward in the long term
5. **Put the message where the action is:** messages must be sent in the right moment, according to patient daily activity. The closer a reminder is to the time and place of the related activity, the more effective it will be.
6. **Provide an objective:** showing health risk and the corresponding steps to reduce it (i.e. a risk assessment associated to being overweight can be accompanied by an action plan of starting a Losing Weight goal).
7. **Invoking trust authorities:** messages must refer to best-practices from health authorities such as AHA and WHO, offering simple and understandable guidelines.
8. **Positive or gain-framed:** messages must emphasise the benefits of an activity, transmitting the information in a positive way and so avoiding possible reluctance from patients. Patients would rather be informed of negative news directly by their doctors and not from an external system. Moreover, most research argue that gain-framed messages are the most persuasive (Grady et al. 2011) (Rothman & Salovey 1997).
9. **Simple content, never mixing different kinds of information:** mixing too much information in a single message may mislead patients and cause them to ignore the messages. Messages must be plain, easily understandable and provide relevant content.

10. **Never too many:** it is more effective to send messages in the proper frequency than to release them every time an event occurs or the patient does not follow the guidelines. One effective message will generate more reaction in a patient than several repeated messages, which may cause reluctance.

The ten guidelines can be applied in general to each message. Even so, the professional can choose to apply only some of them, specific for that patient's behavioural profile. The selection of the guidelines is also based on the patient's current treatment status.

Technology Persuasion Principles (TPP)

Principles of persuasive technologies based on (Fogg 2003) have been applied. In particular, the type of message and the delivering time depend on:

- *Daily attitude:* Attitude is determined from the analysis of the Patient Monitoring device (PMD) usage by the patient and from patient adherence. The numbers and the level of the AFM depends on different indicators, including the patient adherence or his/her behaviour when reading a message. For example, a patient that forgot to measure his/her glycaemic input before start eating will receive a Reminder from the system. If the patient ignores the system advices, the usage indicator related to the Nutrition treatment will decrease over the time, therefore the system will stop sending him/her a reminder and will send a Warning message.
- *Daily state of mind:* the measurement of the patient state of mind allows the system to establish autonomously when to deliver an appropriate message. To deliver contextualised information, the technology would have to determine, among other things, what kind of mood individuals are in. For example, when people are in a good mood, they are more open to persuasion. On the contrary, while a patient is in a bad mood the technology might backfire. Based on these assumptions, when the module responsible to analyse the behaviour receives such inputs, it reacts accordingly by modifying the number and the frequency of the message.

4.1.3 Technological Framework mHealth Implementation

4.1.3.1 User Centered Design G-OD

User-Centered Design (UCD) is a design philosophy and a process that aims to involve users in the design, development and evaluation of systems and products. The aim of UCD processes is to satisfy the needs and expectations of the final users

of the system or product under development, through their participation in the different phases of the development process. UCD processes aim also to build usable applications and to guarantee a satisfactory user experience (Norman & Draper 1986).

There are four main rules that aimed to guarantee the usability of the design:

1. To clearly state which are the possible actions at each moment.
2. To provide visibility of the objects, including the conceptual model of the system, the possible alternative actions and the results of the actions.
3. To facilitate the assessment of the system status.
4. To provide a natural mapping between intentions and required actions, between actions and effective outcome, and between the information that is visible and the interpretation of the system status.

Among the methodologies based on UCD, The Goal Oriented Design (G-OD) focus on the tasks that the patients have to perform, while others focus on modelling the users that will become the target of the product. G-OD combines ethnographic techniques, interviews with stakeholders, detailed user models, scenario-based design and a core set of interaction principles and models. G-OD focuses on modelling the behaviours of the target users and to transform these models into detailed system specifications. The G-OD methodology comprises 6 stages, shown in Figure 34: Research, Modelling, Requirements, Framework, Refinement and Support.

Figure 34. G-OD methodology

The implementation of the Engagement Behavioural Framework was based on the G-OD methodology. Figure 35 shows a scheme that illustrates the main phases for the implementation of the framework.

Figure 35. Scheme of the EBF User-Centered Methodology

4.1.3.2 Use Cases Development Table

Use case analysis is an important and valuable requirement analysis technique that is widely used in modern software engineering. The software requirements are being elicited through the elaboration of relevant use cases. The use case elaboration requires a strong interaction among the stakeholders. Where appropriate, use cases are accompanied by interaction diagrams, describing the interactions going on among components of the platform and their users.

4.1.3.3 Rational Unified Process (RUP)

The RUP – Rational Unified Process is a method for software development based and developed on the open version UP (Unified Process) by the company Rational Software, later bought by IBM. The four base Phases of the project lifecycle of RUP are Inception, Elaboration, Construction and Transition. These Phases represent one full cycle of the project.

The best description of the whole process used for the management of projects using the RUP can be seen on Figure 36.

Figure 36. Description of Rational Unified Process

As shown, the RUP is a method with iterative cycles, where each cycle makes use of several “Disciplines”. The waterfall scheme is used for each of the iteration as well for the whole “Phases” to ensure the final goal is reached, while the built-in spiral-like iterations make the method flexible.

4.1.4 Diabetes Management Indicators

The following methods have been applied to evaluate the impact of the overall system on the diabetes management. The methods, based on a set of surveys for patients and professionals involved in the trial, include assessment of usefulness of the overall system in terms usability, quality of educational intervention, valuation disease self-control.

4.1.4.1 Perceived Usefulness

Perceived usefulness is the factor that indicates the degree that the person believes the information system will assist them in the performance of their job. Perceived ease of use is the second factor, which is used to indicate how difficult the person believes the proposed system would be to use (Davis 1989). Based on the Perceived Usefulness guidelines, a survey of six questions has been designed to assess the usefulness of the EBF within diabetes treatment for both clinical professionals and patients. Each question of the survey is scored on a scale of 1-5.

4.1.4.2 Assessment of knowledge topic importance

The Assessment of knowledge is one of the surveys patients are asked to fill in, in order to determine the state of change patients before the care plan starts. Patients

are asked to indicate how important they considered knowledge about eight different topics related to health management of diabetes. These inputs are used by professionals to appraise patients' perceived importance of their disease and the associated stage of changes applied to the transtheoretical model of intervention.

4.1.4.3 Appraisal of Diabetes Scale

The Appraisal of Diabetes Scale (ADS) survey is a brief self-reported questionnaire containing seven items designed to assess an individual's appraisal on diabetes control. Patients are asked to rate on a 5 point Likert scale to 7-item self-report scale statement. The scale's author state that the ADS can be incisive as a relatively quick screening tool to examine a patient's adjustment to diabetes or the risk for non-compliance with a care regimen. The test is easily administered and is simple to score and interpret.

4.1.4.4 Adoption of Good Practices Survey

The Adoption of Good Practices for diabetes is a questionnaire to assess good practices in chronic disease self-management that has been derived from the Diabetes Treatment Satisfaction Questionnaire (DTSQ) (Bradley 1994). The DTSQ has been designed to make the initial assessment of total diabetes treatment satisfaction in specific areas and perceived frequencies of hyperglycaemia and hypoglycaemia. Each of the presented items of the survey is scored on a scale of 1-5. The DTSQ was originally developed in the early 1980s. It has been used extensively in clinical trials and in routine clinical monitoring and has been translated into more than 40 languages. The DTSQ has been modified to measure treatment satisfaction for other conditions including HIV, renal failure and diabetic retinopathy.

4.1.4.5 Control Preferences scale

A spectrum of patient autonomy exists in active involvement in making decisions. Some patients want complete authority in deciding their therapy while others do not wish to be involved at all. Younger patients and those with higher education are more likely to want to be involved. In general, the more severe the disease, the less autonomy is desired. These types of patient preferences need to be identified early on (Degner et al. 1997). This is an unmet competency for many physicians that can easily be overcome by using the Degner scale, also named "Control Preferences Scale" (CPS). The CPS was developed to measure a construct that emerged from a grounded theory of how treatment decisions are made among people with life-threatening illnesses. The control preferences construct is defined as "the degree of control an individual wants to assume when decisions are being made about medical treatment." The CPS consists of five cards that each portrays a different role in treatment decision-making, using a statement and a cartoon. These roles

range from the individual making the treatment decisions, through to the individual making the decisions jointly with the physician, to the physician making the decisions. The CPS involves subjects in making a series of paired comparisons to provide their total preference order over the five cards. These preference orders are analysed using unfolding theory to determine the distribution of preferences in different populations and the effect of co-variables on consumer preferences. The scale has been tested in a variety of populations, ranging from the general public to highly stressed groups. The CPS has proven to be a clinically relevant, easily administered, valid, and reliable measure of preferred roles in health-care decision-making.

The CPS scale for eliciting patient's input in treatment decision-making is based on the following questions:

- I prefer to make the final selection about which treatment I receive.
- I prefer to make the final selection of my treatment after seriously considering my doctor's opinion.
- I prefer that my doctor and I share responsibility for deciding which treatment is best for me.
- I prefer that my doctor make the final decision about which treatment will be used, but seriously considers my opinion.
- I prefer to leave all decisions regarding my treatment to my doctor.

4.1.4.6 Hassenzahl Model

With the emergence of smartphone applications and the continuous growth of the number of applications, it is important to gain knowledge about the encountered user experience of smartphone applications. According to the ISO standard 9241-210 a user experience is a user's perception that is an effect from the anticipated use or use of a product (ISO/DIS, 2009).

The Hassenzahl model focus on investigating to what extent the user experience, measured as the attractiveness, of a smartphone app is influenced by pragmatic qualities, hedonic qualities, identification and stimulation and personal factors of the user during a first impression, anticipated use and the actual use (Hassenzahl et al. 2003). It is further assumed that the effects are moderated by the type of app. To research the influence on the attractiveness of smartphone apps, the instrument of Hassenzahl has been used for this study. The theoretical base of the AttrakDiff

questionnaire is Hassenzahl's model of user experience. In order to assess the user's feelings about the EBF framework with a questionnaire, the AttrakDiff questionnaire was adopted. The questionnaire, prepared for both clinical professionals and patients, consists of 23 groups of seven elements. For each group of questions, opposite adjectives are shown to the user. The elements of each group are arranged on an intensity scale. Each of the average values of a group of elements creates a scale value for pragmatic quality, the hedonic quality and attractiveness.

4.1.4.7 EBF Evaluation Survey

Apart from perceived usefulness of the patients and the professionals toward the overall system, evaluation has been also focused on analysing the EBF performance expectancies. These include measuring the relative advantages and outcome expectations of the functionalities of the EBF. To achieve these points, a survey based on the Unified Theory of Acceptance and Use of Technology (UTAUT) has been created and used. The UTAUT is a technology acceptance model formulated by Venkatesh and others in "User acceptance of information technology: Toward a unified view" (Venkatesh et al. 2012). The UTAUT aims to explain user intentions to use an information system and subsequent usage behaviour, basing on four key constructs: 1) performance expectancy, 2) effort expectancy, 3) social influence, and 4) facilitating conditions. The resulting survey consists of eight questions on a scale of 1-5.

4.2 Materials

4.2.1 METABO Project

The present study is part of the scientific pilot activities of the EU co-funded research project “METABO” [reference: EU-FP7-ICT-2007-1- 216270]. METABO is an information and communication technologies (ICT) effort aiming at designing, building and testing an IT platform to monitor glucose values and lifestyle/ pharmacological factors affecting blood glucose concentrations in patients with diabetes mellitus in real-life situations in order to provide structured information and therapeutic decision support to diabetes caregivers (METABO 2008).

The aim of the METABO project is the improvement of the clinical management of diabetes by using the latest available technologies to define new patient follow-up pathways inside the health care systems and to help diabetic patients to improve their own disease management. This will be achieved by means of developing a technological platform connecting the different factors involved in the process of gathering information, data processing and decision support that will allow the patient and the medical team to acquire and manage a higher level of information compared to the current clinical practice. The final goal of this closed loop among data acquisition, data interpretation and clinical decision is to enhance the knowledge of the disease and, therefore, its treatment, as well as the closed long loop intends to provide the medical professionals with data and information in more detail and objectivity to improve their decisions support.

However, the complexity of diabetes pathophysiology and the relatively high number of environmental factors influencing the daily metabolic profile do not allow researchers to clearly define a “single” diabetic patient and, in turn, a “single” scope for METABO. In fact, every patient is a different case and responds in a different way to the disease, which leads to the impossibility of covering the entire diabetic population by METABO.

For these reasons, the METABO project will not pursue a pathophysiological classification of the disease, but will try to define a situation/ problem-oriented vision of the disease, in order to focus its features and try to address most of the issues that diabetic patients and professionals have to deal with while treating the disease. Therefore, this categorisation does not centre on patient phenotypes, but addresses some specific situations in which patients may develop specific needs.

4.2.2 Mobile Technologies

Mobile technology refers to portable electronic technology which serves as a medium for communication through transmission and reception of information. It includes different versions of mobile phones and handheld tablets such as personal digital assistants and the new generation of tablets such as the iPad (Lyzwinski 2014). Using mobile technologies in eHealth for diabetes management represents a novel approach for improving adherence. This technology can offer the potential to design solutions for helping non-communicable disease patients and health care providers to improve medication-taking behaviour. Mobile technology has increasingly been recognised as a platform for behavioural change interventions. An inherent benefit of mobile devices for health behavioural change interventions is that mobile devices are widely used across the globe, enabling accessibility and scalability of behavioural change interventions at the population level (Dayer et al. 2013).

4.2.3 Windows Mobile Development

Windows Mobile was a family of mobile operating systems developed by Microsoft for smartphones and Pocket PCs. Windows Mobile extends the familiarity of the Windows desktop to Windows® phones. Windows Mobile is based on Windows Embedded CE and supports the .NET Compact Framework. By using the Windows Mobile platform, one can build innovative applications for mobile devices. The platform offers features such as data connectivity that is seamless and has enhanced security; rich API support such as Bluetooth; an extensive range of programming models that includes native code, managed code, and mobile web development; and device resources such as multi-threading.

Windows Mobile development is performed using the .NET framework. The .NET framework is a software framework created by Microsoft for use in creating Windows applications. Programmers write applications using one of the several languages supported by the .NET framework, like C#, and the applications then execute inside of a runtime environment called the Common Language Runtime. For Windows Phone 7, there are two distinct development approaches you can take when creating your application.

To aid development for programmers, .NET Compact Framework v2 SP2 is now pre-installed with the Windows Operating System. Developers and users also have access to Microsoft SQL Server 2005 Compact Edition for storage and retrieval of information. To make use of Windows Mobile specific features, a set of extra classes are provided.

4.2.4 Apple iOS Development Program

iOS is a mobile operating system developed and distributed by Apple Inc. It was originally released in 2007 for the iPhone, iPod Touch, and Apple TV. iOS is Apple's mobile version of the OS X operating system used in Apple computers. In order to develop iPhone Software Development Kit (SDK) applications, the following instruments are needed:

- An Intel-based Mac running Apple OS X. In order to write native applications with the official iOS SDK and test applications in Apple's official iPhone or iPad Simulator must be run, the latest desktop and laptop operating system from Apple.
- An Apple Developer account. This is required to download the iPhone SDK, the Xcode IDE, and the iPhone Simulator. To run the developed apps on a mobile device or publish through them to the iTunes App Store the iPhone Developer Program is needed.
- Xcode. Xcode is an integrated development environment (IDE) that combines the multiple tools necessary to build an iPhone programme into one application.
- iPhone SDK. The iOS SDK is a software development kit developed by Apple Inc. and released in February 2008 to develop native applications for iOS. The application has been developed within the operating system iOS 4 (formerly iPhone OS), available to the public for the iPhone and iPod Touch on June 21, 2010. iOS is a mobile optimised variant of Mac OS X created by Apple Inc.

4.2.5 Medical devices

Medical devices are instruments that are used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purpose through chemical action within, or on the body. A combination of both Body Area Network (BAN) and Home Area Network (HAN) has been employed for the seamless inter-connection of all the elements of the monitoring platform. The BAN and the HAN networks are based on Bluetooth and Universal Serial Bus (USB) connections. A middleware solution according to the above architecture was developed and configured to support the orchestration of these elements. In particular, the medical devices are composed of:

- **Medtronic GuardianRT Continuous Glucose Monitoring System (CGMS).** The CGM system consists of a glucose sensor, a transmitter, and a small

external monitor. This component shows the current glucose levels and the historical glucose trends. It also notifies the user before reaching a low or high glucose limit and if the glucose level rises or falls too quickly. The CGM transmitter is a small, lightweight device that attaches to the glucose sensor, gathers glucose data, and sends it wirelessly to the glucose monitor unit.

- **Bayer ContourLink Glucometer.** The Bayer ContourLink Glucometer is a medical device for determining the approximate concentration of glucose in the blood by Wireless communication with your compatible Medtronic device. It eliminates inaccuracies due to manual entry errors and has Automatic calibration of the Guardian® Real-Time Continuous Glucose Monitoring System after reading blood glucose value.
- **Lifsource UC321BT Weight Scale.** The Life Source UC-321PLS precision bathroom scale is a health care scale offering a 200 kg x 0,1 kg capacity. The health care scale can communicate with a personal computer via Bluetooth technology to export the user results.
- **Bodymedia ArmBand SenseWear.** The SenseWear® Armband is a wearable body monitor. It utilises a combination of sensors that can gather an array of physiological data and derived lifestyle information such as energy expenditure (calories burned), duration of physical activity, number of steps, sleep and waking states, movement, heat flux, skin temperature and galvanic skin response. The SenseWear® Armband can be worn for up to 14 days continuously without changing the battery, storing continuous physiological and lifestyle data.
- **Omron Walking Style HJ720IT Pedometer.** Omron dual axis technology, counts steps whether positioned vertically or horizontally. The sensor stores up to 7 days of information in its memory. It resets to zero at midnight. The Omron Walking Style Pedometer measurements are: six tracking modes, track steps, aerobic steps, time, distance, calories and fat grams burned. Two kinds of steps can be tracked: regular step and brisk step.
- **Omron M10IT Blood Pressure.** The OMRON M10-IT is a fully automatic blood pressure monitor, operating on the oscillometric principle. It measures the blood pressure and pulse rate.

4.2.6 Medical Panel platform

4.2.6.1 Java Programming Language

The Medical Panel was developed in Java. Java is a general-purpose computer programming language that is concurrent, class-based, object-oriented and specifically designed to have as few implementation dependencies as possible. One design goal of Java is portability, which means that programmes written for the Java platform must run similarly on any combination of hardware and operating system with adequate runtime support. This is achieved by compiling the Java language code to an intermediate representation called Java bytecode, instead of directly to architecture-specific machine code. Java bytecode instructions are analogous to machine code, but they are intended to be executed by a Virtual Machine (VM) written specifically for the host hardware. End users commonly use a Java Runtime Environment (JRE) installed on their own machine for standalone Java applications, or in a web browser for Java applets.

Standard libraries provide a generic way to access host-specific features such as graphics, threading, and networking.

4.2.6.2 Apache Tomcat

Communication between the Medical Panel and Patient platform has been managed through web services developed in Apache Tomcat. Apache Tomcat, often referred to as Tomcat, is an open-source web server developed by the Apache Software Foundation (ASF). Tomcat implements several Java EE specifications including Java Servlet, JavaServer Pages (JSP), Java EL, and WebSocket, and provides a "pure Java" HTTP web server environment for Java code to run in. Tomcat is developed and maintained by an open community of developers under the auspices of the Apache Software Foundation, released under the Apache License 2.0 license, and is open-source software.

4.2.7 LimeSurvey

LimeSurvey (formerly PHPSurveyor) is a free and open source on-line survey application written in PHP based on a MySQL, PostgreSQL or MSSQL database, distributed under the GNU General Public License. As web server-based software it enables users using a web interface to develop and publish on-line surveys, collect responses, create statistics, and export the resulting data to other applications. LimeSurvey is a web application that is installed to the user's server. After installation users can manage LimeSurvey from a web-interface. Users can use rich text in questions and messages, using a rich text editor, and images and videos can be integrated into the survey. The layout and design of the survey can be modified under

a template system. Templates can be changed in a WYSIWYG HTML editor. Additionally, templates can be imported and exported through the template editor. Once a survey is finalised, the user can activate it, making it available for respondents to view and answer. Likewise, questions can also be imported and exported through the editor interface. LimeSurvey has no limit on the number of surveys a user can create, nor is there a limit on how many participants can respond. Aside from technical and practical constraints, there is also no limit on the number of questions each survey may have.

Questions are added in groups. The questions within each group are organised on the same page. Surveys can include a variety of question types that take many response formats, including multiple choice, text input, drop-down lists, numerical input, slider input, and simple yes/no input. Questions can be arranged in a two-dimensional array, with options along one axis based on the questions on the other axis.

4.2.8 Materials for Statistical Analysis

Microsoft Office 2010 and IBM SPSS Statistics 20 have been used for statistical analysis results.

Chapter 5

Results

Nowadays mobile technology is largely accessible by most of the population. Thanks to increased processing power, better battery life, larger screen sizes and vastly improved networking speeds, the corresponding mobile health apps potential has grown greatly. On the other hand, the behavioural changes techniques studies, applied to CDs such as diabetes have shown to be highly helpful and wide open to many prospects of possible ICT solutions.

Therefore, in combining the mHealth technology with the behavioural change techniques, we could define a new framework for diabetes care that could really support the disease management for both health patients and professionals during daily life. In this chapter a conceptual framework is described for tailoring diabetic patients towards the prescribed adherence treatment and for supporting the health professional in the patient's follow up. Thereafter the framework has been characterised and validated within the context of the METABO system.

5.1 Treatment Adherence and Usage Adherence: Indices Definition

Adherence to care plan is a multi-dimensional problem and not always easy to perform. As part of the framework, we suggested a set of indices to estimate the patient's willingness to use the medical system and their adherence to the treatments. In order to comprehend in depth these indices, the following definitions are needed:

- A healthcare **system** is a software application installed in a technology device the patients use to monitor and treat their disease.
- The **system usage** represents the utilisation of the system by patients for managing their healthcare.
- The **adherence to the system usage** (or usage adherence) refers to the extent to which the patients use their medical system according to their doctors' recommendations.
- The **adherence to the treatment** (or treatment adherence) is the extent to which the patients agree on a medical treatment that includes doctor's prescriptions and recommendations.

Treatment adherence and the usage adherence are calculated through five care plan dimensions: Nutrition (NU), Physical Activity (PA), Medication (ME), Measurements (MS) and Education (ED). ME dimension is composed of three sub-dimensions: Glycaemic Level (GL), Weight (WE) and Blood Pressure (BP).

5.1.1 Definition of the Treatment Adherence Equations

The methodologies applied to define the indices for the assessment of care plan are described in 4.1.1.

5.1.1.1 Nutrition Treatment Adherence Equation

Nutrition adherence corresponds to the compliance of the individual in following a diet plan. A basic parameter to control the individual behaviour of food intake is to set a Recommended Daily Kilocalories (RDK) index, consisting of the maximum amount of kilocalories a patient should have within a day. This parameter is chosen by the nutritionist and updated if needed. The measure of the NU treatment adherence, calculated in a time period, must take into account the ratio between patient intake and prescription during a day.

Considering the variables:

Nd : number of days

Nm : number of meals

$Meal_Kcal_i$: number of kilocalories j per meal in day i

$RDKcal$: Recommended Daily Kilocalories

The equation representing the estimation of the adherence in NU is represented in Equation 1 Nutrition Treatment Adherence (NU_TA):

Equation 1 Nutrition Treatment Adherence

$$NU_TA: \quad 1 - \left(\frac{\sum_{i=1}^{Nd} \left(\sum_{j=1}^{Nm} Meal_Kcal_{ij} \right) - RDKcal \cdot Nd}{RDKcal \cdot Nd} \right) \quad (\text{Equation 1})$$

NU_TA index consist on the percentage of the ratio between the ingested kilocalories per day and a Recommended Daily Kilocalories (RDKcal) index. RDKcal index value is set by the nutritionist.

5.1.1.2 Measurement Treatment Adherence Equation

Considering the variables:

Nd : number of days

$Hypo_i$: hypoglycaemic event in day i

$Hyper_i$: hyperglycaemic event in day i

δ : number of expected instable glycaemic events

The equation representing the estimation of the treatment adherence of GL is represented in Equation 2 Glycaemic Level Treatment Adherence (GL_TA):

Equation 2 Glycaemic Level Treatment Adherence

$$GL_TA: \left(1 - \min \left(\sum_{i=1}^{Nd} Hypo_i + \sum_{i=1}^{Nd} Hyper_i \right), \delta \cdot Nd \right) \% \quad (\text{Equation 2})$$

GL_TA corresponds to the percentage of the number of hypo/hyperglycaemic episodes compared with the number of expected unstable hypo/hyperglycaemic events in Nd days.

Considering the variables:

Nd : number of days

we_{max} : maximum weight

we_i : weight input in day i

The equation representing the estimation of the adherence of WE index is represented in Equation 3 Weight Treatment Adherence (WE_TA):

Equation 3 Weight Treatment Adherence

$$WE_TA: \left(we_{max} / \left(\sum_{i=1}^{Nd} we_i \right) / Nd \right) \% \quad (\text{Equation 3})$$

WE_TA corresponds to the percentage calculated from the ratio between the established maximum weight and the average weight measured during a period.

Considering the variables:

Nd : number of days

Bp_sy_{max} : maximum systolic pressure

Bp_di_{max} : maximum diastolic pressure

Bp_sy : systolic pressure input

Bp_di : diastolic pressure input

The equations representing the estimation of the adherence of BP indices are represented in Equation 4 Blood Pressure Systolic Treatment Adherence ($BPSY_TA$) and Equation 5 Blood Pressure Diastolic Treatment Adherence ($BPDI_TA$):

Equation 4 Blood Pressure Systolic Treatment Adherence

$$BPSY_TA: \left(bp_sy_{\max} / \left(\sum_{i=1}^{Nd} \sum_{j=1}^{Nm} bpsy_{ij} \right) / Nd \right) \% \quad (\text{Equation 4})$$

BPSY_TA corresponds to the percentage calculated from the ratio between the established maximum level of systolic blood pressure and the average of systolic blood pressure measured during a period.

Equation 5 Blood Pressure Diastolic Treatment Adherence

$$BLDI_TA: \left(bp_di_{\max} / \left(\sum_{i=1}^{Nd} \sum_{j=1}^{Nm} bpdj_{ij} \right) / Nd \right) \% \quad (\text{Equation 5})$$

BPDI_TA corresponds to the percentage calculated from the ratio between the established maximum level of diastolic blood pressure and the average of diastolic blood pressure measured during a period.

5.1.1.3 Medication Treatment Adherence Equation

Medication treatment adherence for a diabetic patient corresponds to the compliance of the individual in medicine intakes, consisting of anti-diabetic drugs and insulin medications. A medical treatment can differ from one day to another, therefore the measure of the treatment adherence, calculated in time period, must take into account the ratio between patient inputs and prescriptions for each single day.

Considering the variables:

Nd: number of days

Nm: number of drug input

Ni: number of insulin input

MD_{ij}: medication input *j* in day *i*

II_{ij}: insulin input *j* in day *i*

PrMD_{ij}: prescribed medication input *j* in day *i*

PrII_{ij}: prescribed insulin input *j* in day *i*

The equation representing the estimation of the treatment adherence of MD index is represented in Equation 6 Medication Treatment Adherence:

Equation 6 Medication Treatment Adherence

$$MD_TA: \quad \left(1 - \left(\sum_{i=1}^{Nd} \sum_{j=1}^{Nm} MD_{ij} + \sum_{i=1}^{Nd} \sum_{j=1}^{Ni} II_{ij} \right) / \left(\sum_{i=1}^{Nd} \sum_{j=1}^{Nm} PrMD_{ij} + \sum_{i=1}^{Nd} \sum_{j=1}^{Ni} PrII_{ij} \right) \right) \% \quad \text{Equation 6}$$

MD_TA corresponds to the percentage of the ratio between drug and insulin intake number compared with the prescribed drugs and insulin.

5.1.1.4 Physical Activity Treatment Adherence Equation

The measure of the treatment adherence in physical activity comes from the activities performed in a week based with respect to the physical exercises prescribed. Activity is calculated through the multiplication of the number of MET with the time spent.

Considering the variables:

Nw : number of weeks

$METS_{ij}$: METs related to a physical activity in week i and day j

$Tact_{ij}$: time dedicated to the physical activity in week i and day j

$PrPA_i$: prescribed physical activity in week i

The equation representing the estimation of the PA treatment adherence is represented in Equation 7 Physical Activity Treatment Adherence (PA_TA):

Equation 7 Physical Activity Treatment Adherence

$$PA_TA: \quad \left(\sum_{i=1}^{Nw} \sum_{j=1}^7 METs_{ij} \cdot Tact_{ij} \right) / \sum_i Pr PA_i \% \quad \text{Equation 7}$$

The amount of the treatment adherence PA_TA is equal to the percentage ratio between the performed activities over one or more weeks and the related prescription.

5.1.1.5 Education Treatment Adherence Equation

The measure of the treatment adherence in ED is calculated from the summation of the questionnaire results performed, divided by the number of the prescribed quizzes over one or more weeks.

Considering the variables:

Nw : number of weeks

QR_i : questionnaire results in day i

$PrED_i$: prescribed quizzes in day i

The equation representing the estimation of the ED treatment adherence is represented in Equation 8 Education Treatment Adherence (ED_TA):

Equation 8 Education Treatment Adherence

$$ED_TA: \left(\sum_{i=1}^{Nw} QR_i \right) / \sum_{i=1}^{Nw} Pr ED_i \% \quad \text{Equation 8}$$

5.1.2 Definition of the Usage Adherence Equations

The methodologies applied to define the indices for the usage adherence estimation are described in 4.1.1.

5.1.2.1 Nutrition Usage Adherence Equation

Nutrition usage adherence is calculated from the compliance of the individual in following a diet plan. NU_UA index corresponds to the percentage of data of meals inputs, divided by the total number of prescribed meals during a period. The measure of the NU usage adherence, calculated in a time period, must take into account the ratio between the patient intake and prescription during a day.

Considering the variables:

Nd : number of days

N_Meal_i : number of meals in day i

N_PrNU_i : number of prescribed meals in day i

The equation representing the estimation of the usage NU is represented in Equation 9 Nutrition Usage (NU_UA):

Equation 9 Nutrition Usage Adherence

$$NU_UA: \left(\left(\sum_{i=1}^{Nd} N_Meals_i \right) / N_Pr NU \right) \% \quad \text{(Equation 9)}$$

5.1.2.2 Measurement Usage Adherence Equation

Considering the variables:

Nd : number of days

Ngl_checks_i : number of glycaemic self-checks in day i

Nd_PrGL_i : number of prescribed glycaemic self-checks in day i

N_Hyp_i : number of hyperglycaemic events in day i

The equation representing the estimation of the ME index usage adherence applied to glycaemic level is represented in Equation 10 Glucose Level Usage Adherence (GL_UA):

Equation 10 Glucose Level Usage Adherence

$$GL_UA: \left(\left(\sum_{i=1}^{Nd} Ngl_checks_i \right) / \sum_{i=1}^{Nd} Nd_PrGL_i + \left(\sum_{i=1}^{Nd} Ngl_checks_i \right) / \sum_{i=1}^{Nd} N_Hyp_i \right) \% \quad (\text{Equation 10})$$

GL_UA index is calculated as the percentage of glycaemic self-checks received during a period, with respect to the expected and recommended measurements. Recommended measurements are referring to the glycaemic self-checks to be performed after a hypo/hyper event.

Considering the variables:

Nd : number of days

Nwe_checks_i : number of weight self-checks in day i

Nd_PrWE_i : number of prescribed weight self-checks in day i

The equation representing the estimation of the WE index usage adherence is represented in Equation 11 Weight Measurement Usage Adherence (WE_UA):

Equation 11 Weight Measurement Usage Adherence

$$WE_UA: \left(\left(\sum_{i=1}^{Nd} Nwe_checks_i \right) / \sum_{i=1}^{Nd} Nd_PrWE_i \right) \% \quad (\text{Equation 11})$$

Blood Pressure usage adherence is calculated from the compliance of the individual in measuring their own systolic and diastolic blood pressure according to the medication plan.

Considering the variables:

Nd : number of days

Nbp_checks_i : number of systolic and diastolic blood pressure self-checks in day i

Nd_PrBP_i : number of prescribed systolic and diastolic blood pressure self-checks in day i

The equation for the estimation of the BP index usage adherence is represented in Equation 12 Blood Pressure Usage Adherence (BP_UA):

Equation 12 Blood Pressure Usage Adherence

$$BP_UA: \left(\left(\sum_{i=1}^{Nd} Nbp_checks_i \right) / Nd_Pr\ BP \right) \% \quad (Equation\ 12)$$

5.1.2.3 Medication Usage Adherence Equation

Medication usage adherence for a diabetic patient corresponds to the compliance of the individual in medicine intakes, consisting of anti-diabetic drugs and insulin medications. A medical treatment can differ from one day to another, therefore the measure of the usage adherence, calculated in time period, must take into account the ratio between patient inputs and prescription for each single day.

Considering the variables:

Nd : number of days

Nm : number of drug input

Ni : number of insulin input

MD_{ij} : medication input j in day i

II_{ij} : insulin input j in day i

$PrMD_{ij}$: prescribed medication input j in day i

$PrII_{ij}$: prescribed insulin input j in day i

The equation representing the estimation of the adherence of MD index is represented in Equation 13 Medication Usage Adherence (MD_UA):

Equation 13 Medication Usage Adherence

$$MD_UA : \left(1 - \left(\sum_{i=1}^{Nd} \sum_{j=1}^{Nm} MD_{ij} + \sum_{i=1}^{Nd} \sum_{j=1}^{Ni} II_{ij} \right) / \left(\sum_{i=1}^{Nd} \sum_{j=1}^{Nm} PrMD_{ij} + \sum_{i=1}^{Nd} \sum_{j=1}^{Ni} PrII_{ij} \right) \right) \% \quad (Equation\ 13)$$

MD_UA is equivalent to MD_TA and corresponds to the percentage of the ratio between drug and insulin intake number compared with prescribed drugs and insulin.

5.1.2.4 Physical Activity Usage Adherence Equation

The measure of the usage adherence in physical activity PA comes from the activities performed in a week base with respect to the physical exercises prescribed.

Considering the variables:

Nw : number of weeks

N_PA_i : number of physical activities in week i

Nw_PrPA_i : number of prescribed physical activities in week i

The equation representing the estimation of the *Physical Activity* index usage adherence is represented in Equation 14 Physical Activity (PA_UA):

Equation 14 Physical Activity Usage

$$PA_UA: \left(\sum_{i=1}^{Nw} N_PA_i \right) / Nw_PrPA\% \quad \text{(Equation 14)}$$

5.1.2.5 Education Usage Adherence Equation

The measure of the usage adherence in ED is calculated from the use of an educational tool and from the learning prescription over one or more weeks.

Considering the variables:

Nw : number of weeks

N_ED_i : number of educational tool usage in week i

Nw_PrED_i : number of prescribed educational tool usage in week i

The equation representing the estimation of the *Education* index usage adherence is represented in Equation 15 (ED_UA):

Equation 15 Education Usage Adherence

$$ED_UA: \left(\sum_{i=1}^{Nw} N_ED_i \right) / Nw_PrED\% \quad \text{(Equation 15)}$$

5.2 Engagement Behavioural Framework

The conceptual framework defined hereby is formalised by means of the materials and the methods exposed in Chapter 4. The conceptual framework has been named Engagement Behavioural Framework (EBF).

The purpose of the EBF is to present a realistic and comprehensive picture of what patients should accomplish in order to benefit from their healthcare treatment. Specifying these behaviours, allows the patients to understand the magnitude and scope of the challenges they face with diabetes. This framework provides a basis for concrete, measurable expectations for individuals' behaviour that should guide the re-orientation of care toward a proper adherence on treatment. It constitutes

a compelling technological solution to track and monitor engagement in CDs, in particular diabetes.

The EBF has been designed to provide, from the patient side, self-management and educational support through automatic and dynamic feedback messages (AFM) about physiological status, warnings, prescription recommendations and lifestyle tips. For example, if the user forgets to perform a physical activity at the gym or to indicate the last breakfast kilocalories information, the EBF will send the corresponding reminder message. Messages are customised, according to patient's needs: if a T2DM patient is less apt to undertake a physical activity plan, the analysis model of EBF may define a specific programme of AFM, orientated to motivate the user while sensitising them through certain educational messages. This approach leads to improving patient's prescription adherence and persuading patients towards a general improvement in diabetes self-management, by means of text messages that are automatically selected and dispatched. Such objectives include the patient's adherence to drug intake, food intake and physical activity prescriptions.

The framework is based on a feedback process that automatically responds to the inputs generated by the patients or under the command of a caregiver. The proposed approach includes all the process chains for generating, selecting and delivering messages. This strategy consists of a generic architectural description applicable to a generic ICT-based disease management system and a set of design recommendations related to:

- Rules for composing personalised messages.
- Input data to be considered for generating feedback.
- How to include historical data about user interaction into the rules.

The decision of defining the EBF into the mobile health domain was principally dictated from the need to having a technological solution capable of:

1. Allowing the care provider to remotely dispatch and update the patient treatment plan, while supervising the follow-up;
2. Providing the patient with an electronic diary for regularly taking control of the care plan and for addressing the treatment inputs during the whole day;
3. Allowing remote communication between patient and care provider;
4. Allowing patients to download physiologic measurements from medical devices and sensors and integrating the data into one single device;

5. Analysing and autonomously managing the current adherence levels in real-time.

The EBF is designed to be integrated in a mobile application, like a patient monitoring device, used as an electronic medical diary or an adherence reminder application tool. The framework is in charge of automatically sending AFMs to patients, chosen according to a multi-dynamic set of parameters, and processing the behavioural responses received from patients for training the framework towards a more appropriate AFM. The AFMs are categorised in different subgroups according to the patient characterisation performed by the healthcare professional. The aim of this innovative approach is to improve the effectiveness of the set of selected AFMs gained from iterations. The sub-paragraph 5.1.4.1 is dedicated to describing and illustrating the AFM.

As discussed earlier, diabetic patients, T1DM but particularly T2DM, have years or even decades of unhealthy habits and are unlikely to change those customs based on a common series of text recommendations coming from their mobile encouraging them to eat more fruits and vegetables. On the contrary, a main purpose of this research work was, from the beginning, to design a smart solution, able to assist patients in being more independent and thus, improve their self-management while reducing the primary needs from the healthcare team. The EBF is an instrument that supports the diabetic patient in the short and long term, in consonance with the type of subject and circumstances in which the benefit can be most effective. In this context, the employment of an interactive behavioural approach is a potential resource for improving the effectiveness of diabetes management and promoting and sustaining the patient toward a behavioural change.

Among the different variables that this solution has to consider, the EBF contemplates the variety of socio-demographic characteristics of diabetic persons. As an example, people with limited functional health literacy or people with a low level of technology confidence. Moreover, the benefits of these technologies are not always equally distributed across patients. Many patients already have the resources they need to effectively manage their illness and may receive little benefit from the types of support that are possible through the EBF. At the opposite extreme, are patients with problems, such as an unstable residence or other serious needs, who lack the basic resources to take advantage of this additional support. Rather, EBF may be of greatest benefit to the large number of patients with an interest and basic capacity to improve their diabetes care but who need the additional support for self-monitoring and self-management information that a mHealth system can provide. Finally, just as clinicians do not prescribe the same hypoglycaemic drug in

the same dose to all of their patients, the health professionals need the instruments for matching the right medical approach to the right patient at the right time.

A preliminary study, conducted within a first baseline analysis, is dedicated to delineate the problem associated to the diabetic patient. This step is essential to understand, one by one, the relevant factors that influence patients' adherence behaviour. An integrated set of behavioural change theories applied to healthcare are selected to allow the EBF to identify the proper care, interpreting a patient's reaction to treatment and managing its follow-up in the short and long term.

Within the EBF a new design of mHealth solution has been defined, basing on health behaviour programmes, chosen among the broad heterogeneity of approaches for addressing self-management and improving adherence in diabetes. Research suggests that the most effective behavioural change interventions, especially applied to CD, are those that use multiple strategies and aim to achieve multiple goals of awareness, recommendation, transmission and skill development in self-management.

More concretely, four instruments have been employed:

1. Transtheoretical model (TTM)
2. Goal-Setting Theory of Motivation (GST)
3. Guidelines from Effective Health Communication (EHC)
4. Technology Persuasion Principles (TPP)

These methods have been applied at different stages and at different levels of the treatment process. The TTM model has been used for setting the dispatch of tailored feedback messages by the system during the therapy period and its main views have been captured from the analysis of messages from patients during the treatment. The GST is based on self-monitoring, self-judgement, and self-evaluation. With regard to self-evaluation, the theory proposes specific mechanisms that may directly influence it, such as gaining self-respect for goal completion or progress. The goal-setting method has been centred on two targets: achieving a specific weight and/or improving the educational knowledge on diabetes in a determined period. Finally, the AFMs were designed according to a different set of guidelines EHC and pervasive health technology approaches (TTP or PT). Figure 37 shows the principal solutions for each applied theory, guidelines and principles, which have contributed to the messages definition.

Figure 37. AFM definition

A main objective of the EBF includes encouraging individuals in following a healthy diet, teaching them to distinguish between, and choosing an active lifestyle instead of a sedentary one, comprehending the disadvantages of having bad habits and acquiring social and knowledge skills on diabetes self-control. As depicted in Figure 38, the EBF aims to build a continuum follow-up of the diabetic patient, using behavioural and physiological analysis among each individual treatment phase. The first state encompasses a complete screening study of the individual (Baseline), the second state refers to individual self-managing activities and the third state is dedicated to the patient's treatment adjustment.

Figure 38. EBF behavioural and physiological treatment strategy

From the first phases of the EBF's model definition, a primary objective was the selection of the behavioural methods that could support user" during his/her daily

life. Such a solution should be highly customisable and able to provide tailored recommendations.

The usage of a monitoring system can be demanding for the user, since it requires the usage of sensors, which may feel uncomfortable on certain occasions, and a great interaction with the PMD. For this, the design of the system must be focused on addressing and remedying these inconveniences, as well as motivating the patients to use the applications and pay attention to the recommendations and feedback messages.

The AFMs are defined to encourage certain attitudes and actions from patients. This includes messages that must be adapted to their individual necessities. Initial personalisation comes from the medical doctors, who must identify the primary needs of patients during the baseline consult and include the corresponding outcomes in the system. Further steps of personalisation come from the recurrent process of analysis of patient's adherence and patient's device usage. These inputs will be used for the identification of the behavioural trends of the patient. In particular, the system will use the data to identify the corresponding list of AFMs. During the application usage, patients can always control the type of message they want to receive and to avoid being overwhelmed.

During the closed loop process, AFMs messages pass through three levels of periodic and dynamic filtering:

1. First, the AFM library is chosen from a general AFM repository and adapted according to patient baseline criteria;
2. Before the AFMs are sent to the local PMD repository, the intervention plan is inspected and, if needed, refined by the professional;
3. AFMs are periodically uploaded according to patient's adherence and patient-system usage.
4. The list of AFM can be manually customised by patient, who is able to modify which, how and when an AFM must be dispatched, according to their preferences.

Engagement is reinforced in critical periods when patients tend to relax and move away from their established routines, such as during religious holidays, vacations, and special occasions, compared to their normal daily routines, when the patients will be more stable and more likely to follow the recommended treatment. In those occasions, when patients have changed their environment and it is easy to change

the diet or forget about medication, the EBF plays a very important role, encouraging patients to remain stable and to adhere to their treatments as much as possible.

Education is itself a motivational tool, since most diabetic patients are unaware of the effects of their activities and diet on their condition, beyond the short term effects of their glycaemic levels. Long term conditions are often underestimated and therefore, making patients aware of the positive effects that certain changes in their lifestyle may have on their future condition can motivate them to comply with their doctors' recommendations. On the other hand, a deep knowledge of the disease and their condition will always help them improve their self-management and in taking decisions affecting their treatment.

Educational content will be available for patients on demand but patients will also be able to enable a feature that will release educational tips or messages randomly related to the subjects the patient is interested in. Patients can, for instance, receive a message stating the benefits of aerobic exercise on a daily basis if they are interested in physical activity, or a message on the differences between having fructose instead of regular glucose if they are more interested in nutrition.

5.2.1 Automatic Feedback Message (AFM)

The AFM represents the message patients receive while interacting with the EBF. During daily life, the patient is asked to provide dietary information, physical activity performances, medication intakes, metabolic measurements and educational questionnaire inputs. Based on the patient's behaviour, the system reacts with AFM. A central system repository contains the entire set of AFM, pre-defined by professionals (i.e.: educational specialists, medical doctors, nutritionists and physiologists). A message content is determined univocally, according to the following tags:

- *Level*: Refers to the level of priority an AFM may have. Four levels of AFMs are defined:
 1. **Warning (Level 1)**: Consists of high priority messages, tied to a critical issue. Critical issues can be associated to both asynchronous events, related to the current day's activities (i.e.: the patient forgets to take a medicine or has high blood pressure), and to synchronous events, activated from periodically measurements triggers.
 2. **Reminder (Level 2)**: Refers to a low priority message, for instance the patient did not perform physical activities in the past week or the patient did not fill in a scheduled educational quiz. Reminder

notifications can be associated to both asynchronous and synchronous events.

3. Tip (Level 3): Consists of smart suggestions to manage the disorder and overall health and lifestyle. Tip notifications can be associated to both asynchronous and synchronous events.
 4. Goal (Level 4): These AFM are only focused on reinforcing the patient's behaviour towards the achievement of the objective goal. It can be correlated to a short or long term period. Two examples are: improving knowledge of health risks through educational quizzes; and reinforcing the awareness on nutrition habits and reaching an ideal weight according to the Body Mass Index (BMI).
- *Dimension (Dim)*: A dimension refers to the section of the treatment plan the message is referring to. There are five main dimensions: NT, PA, MD, ME and ED.
 - *Topic*: topics are used to identify the issue related to the selected topic. Each topic can be related to different reasons. As an example, the "amount of carbohydrates eaten" and the "total amount of Kilocalories for a day" are two topics of the nutrition topic. Subtopics are identified with an identification number. The number is not pre-determined and depends on the topic.
 - *Segments*: In order to provide an extensive user-oriented screening and to better de-lineate the patient profile, different major scenarios, called segments, are considered. Specifically, six clinical situations are identified in order to characterise the type of diabetic patient and the corresponding nature of metabolic control:
 1. Changes in the environment (like international travelling or working night shifts): in this situation a diabetic patient is exposed to different bio-rhythms, different food, different habits in terms of physical activity, creating the background for a loss of control even in previously well compensated patients.
 2. Physical exercise: physical activity is known to favour glucose consumption by the muscles (as well as weight loss, improvement in insulin sensitivity, and several other positive effects) leading to the use of exercise as part of the treatment strategy of the patient, but also exposing the patient to the risk of hypoglycaemic episodes, especially in young diabetic athletes.

3. Sudden hypoglycaemia prediction: the occurrence of an episode of severe hypoglycaemia, especially if not preceded by early symptoms (the so-called “unaware hypoglycaemia”) can put the patient in serious danger, especially during activities requiring a high level of concentration such as driving, operating heavy machinery, playing “extreme” sports.
 4. Lack of motivation: the absence of a continuous motivational support and/or the presence of problems in accepting the disease and coping with the required changes in lifestyle can lead to a situation in which the traditional medical approach is impotent because of the lack of everyday compliance by the patient.
 5. Unstable diabetes control: this segment includes all patients with a lack in diabetes control despite the best available treatment. It is the most complex clinical scenario, embracing the other five and providing the common ground of the platform structure.
 6. Co-morbidity disease management: the co-presence of diseases other than diabetes, diabetes related complications, or organ failure, has a tremendous impact on glucose control and treatment efficacy/ safety.
- *Type of diabetes*: messages are addressed according to the type of diabetic patient, T1DM, T2DM and Gestational Diabetes.
 - *Stage of change*: the system must be able to address certain messages according to the current patient’s behaviour, divided into five stages of change: pre-contemplation, contemplation, preparation, action, and maintenance. The individual's cognitive and behavioural levels differ from stage to stage and this implies a TTM-based tailored intervention. The stages of TTM include: identifying the current level of education of a patient, the level of self-management and the level of engagement.
 - *Mood*: The expression with which a statement, like a text message, is presented and then understood by a patient varies according to their state of mind. This is because the short-term fluctuations in mood during a day have significant effects on how a message is interpreted. In order to gather this information and allow the system to react accordingly, the patient is asked to entry the current state of mind among five options, represented by five emoticons:
 1. Angry (A)
 2. Calm (C)
 3. Exited (E)

4. Happy (H)

5. Unhappy (U)

Emotional states were chosen from P. N. Johnson-Laird's & Keith Oatley's theory of the emotions (Johnson-Laird & Oatley 1989).

Based on the aforementioned tags, the text message of an AFM is univocally represented. An example of how the AFMs are categorized in the AFM library is shown in Table 5.1.

Table 5.1. Example of an AFM Library

ID	Level	Dim	Topic	Segment	Type	Stage	Mood	Text Message
01	1	NU	2	2	1	3	H	"Did you have your lunch?"
02	1	ME	6	2	2	2	H	"Did you take your insulin dose? If yes, please notify the system"
03	3	ED	1	1	2	1	C	"Eat according to your health needs and it will pay off!"
04	4	ED	9	3	3	1	U	"Check your foot carefully after exercise"
05	2	PA	12	4	2	4	A	"You should increase your physical activity, please check your prescription"

To each ID, a corresponding AFM text is associated. The tables illustrating some of the AFMs defined are available in Appendix 8.

5.2.2 Architecture of the EBF

Traditional mHealth platforms are based on sharing medical information between clinicians and patients. These systems do not include persuasive and/or coaching strategies and do not track the user behaviour, limiting their purposes to send the medical treatment from the clinical side, store the patient physiological measurements and lifestyle activity and send them back to the clinical professional that will act accordingly with a refinement of the medical treatment.

Traditional mHealth system

Figure 39. Traditional mHealth System

Based on the user requirement elicitation, the architecture was designed and functional specifications were elaborated. A general overview of a Behavioural mHealth System based on the EBF is represented in Figure 40. As illustrated, the architecture of the system maintains the treatment process, represented with a blue arrow, and integrating the EBF. The framework is represented as a closed loop between the AFM Manager, the Patient Station, the Behavioural Analysis module and the Professional Side, respectively for gathering the entry data, analyse the user behaviour, determine the proper AFM intervention and transmit the information to the clinician. As a result, EBF supports the health professionals, controlling the framework activities and following the patient behaviour while checking patient's prescription adherence.

As shown in Figure 40, EBF intervenes in both the professional and patient side. The following sections describe the modules that compose the framework with the related functionalities.

Figure 40. Engagement Behavioural Framework

5.2.2.1 Professional Side

The Professional Side or *Professional Sub-system (PRS)* consists of four modules: *Professional Station (PRST)*, *Prescription Manager*, *Patient Screening Profile* and *AFM Professional module (AFM PRO)*. The PRST is the Graphical User Interface (GUI) the professional uses executing the care plan, control the patient follow-up and adjust the treatment and the related prescriptions. The Prescription Manager is responsible for managing the medical prescription and retrieving inputs from the patient. Within the follow up, patient data is stored in the PRS Repository and accessed through a patient visualisation data panel.

During the first visit to the medical centre, often called a screening visit, a diabetic patient is submitted to a set of examinations by the doctor. The doctor firstly asks about patient medical history that includes age, life style, complications and previous diabetes treatment plan. This is followed by a complete physical examination. This phase foresees collecting baseline physiologic, clinical and lifestyle data such as height and hip measurements, blood glucose level, systolic and diastolic blood pressure and laboratory tests for measuring clinical data such as HbA1c, cholesterol and fat levels. This information will be used at a later stage to compose an adequate personalised treatment plan.

In the context of EBF, the data collected during this phase, named baseline data, are managed by the Patient Screening Profile module. This module is responsible for collection of all patient data during the screening visit. Data are collected through subdivided categories that include physiological data, clinical data and behavioural data. Behavioural data refers to a multitude of factors that include personal lifestyle habits, such as study time, working time, social activities or information about sleeping. The system makes use of this data, for instance by examining how long or how often certain behaviours occur.

Behavioural data can depend on temporary variables such as the frequency of an information recording, the duration of recording and the interval recorded between lifestyle events. In addition, the feedback of latency recording, calculated when the professional is interested in measuring the time that it takes for the patient to respond to a message, is also a relevant indicator to assess the user behaviour. For example, if a patient forgets to take a medicine and the system makes a request to remind them to take it, the length of time it takes for the patient to comply with the request is inspected. Based on this information, the *Patient Screening Profile* module characterises the patient profile, by identifying them to an appropriated focus area.

Figure 41. Professional Subsystem

To assess patients' preferences in decision making and predicting how better they can benefit from the use of the messages received, patients are involved in responding to a pre-set list of questions related to the type of treatment they wish to receive. This information can either affect the medical prescription, the behavioural intervention and the adherence follow-up.

After the professional has entered the baseline data into the *Patient Screening Profile* module, the first set of medical prescriptions are prepared, stored in the Central Repository and sent to the Patient Side. The prescription can consist of treatment of physical exercise, anti-diabetic and insulin medication, a strict diet or improving disease consciousness through reading personalised topic contents related to diabetes. Patient input data are collected mainly from the biomedical sensors and the manual user inputs into the mobile application and are periodically transmitted to the *PRS*.

The *AFM PRO* is in charge of allowing the professional managing the dispatching of the AFMs messages, beforehand pre-processed in the AFM matching module, to the patient. In particular, the module permits manual intervention on the selection of AFM message from the central *EBF Repository*, inserting new AFMs messages, editing or deleting old ones. After any update, the AFM management module transfers the AFMs into the Patient Side.

5.2.2.2 Patient subsystem (PTS)

The architecture of the Patient Side or Patient Subsystem (*PTS*) is depicted in Figure 42. The sub-system is responsible for:

1. Generating the AFMs
2. Receiving and locally storing the user inputs

3. Evaluating the user behaviour
4. Re-elaborating the AFMs dispatching logic

Furthermore, the *PTS* is constantly connected to the *PRS* for disclosing the user data to the professional, who can interact with the EBF follow-up and intervene in the management of the list of AFMs, named *AFM Library* (Table 5.1). *PTS-PRS* data connection allows the user baseline data to be sent to the patient repository, while the data from the *PTS* are periodically transferred to the *PRS Central Repository*.

Figure 42. View of the closed-loop of the EBF

The local repository contains the basic information about the user, such as clinical profile, laboratory measurements, motivational status, awareness on diabetes disease and computer literacy collected at the clinical centre through medical visits, interviews and surveys. Of course some of these data are not expected to change frequently, since their update can be at most, every six months.

After the first baseline is collected from the Patient Screening Profile module, the data are sent, together with the medical treatment, into the AFM module. From herein, the EBF closed-loop action generates the automatic message intervention through the *AFM Manager*, the Patient Station and the Behavioural Analysis module.

AFM Manager

The *AFM Manager* is in charge of managing the dispatch of AFMs to the patient station, according to the clinical preferences and the patient behaviour. The *AFM Manager* is composed of the *Matching* and the *Scheduler* sub-modules.

The *Matching* module is responsible for retrieving data from the Patient Screening Profile module, the behavioural data from the Behavioural Analysis module and matching this information with the message repository, in order to select the best set of messages. The objective consists of identifying meaningful patients' characteristics, based on treatment needs, attitudes and health care behaviours and makes use of this information to implement messages' engagement strategies. A set of rules based on the behavioural intervention defined in 4.1.2 and included into the module, is responsible for selecting the appropriate messages according to the type of patient.

The time frequency and the number of messages are specified within the rules for short or long term treatments, according to the behavioural information (i.e. patient's aptitude on interacting with the system). This activity is managed by the *Scheduler* sub-module. As an example, the *AFM Manager* counts the number of times a user accepts an AFM or whether they refuse to read it in that moment and skips it (Figure 43). These log inputs allow the system to measure patients' behaviour related to the interaction with the system. The *Matching* sub-module operates autonomously, but shall always work under professional supervision, which may refine the selection of messages through a dedicated interface.

Figure 43. Example of AFM

Patient Station

The *Patient Station (PS)* represents the medical application the patients use, through their own smartphone device. This module operates as a PMD, collecting the data inputs through manual inputs and the metabolic data from a wireless or cable connection with the biomedical sensors. The retrieved information is then

stored in a local database and periodically transmitted to the *AFM Patient* module. The architecture of the PS is illustrated in Figure 44.

Figure 44. Overview of the Patient Station

As mentioned earlier, the local database, called the *EBF Repository*, collects the information related to diet, medication intakes, physical activity, receipt of dispatched messages, answers to quizzes and sensor data. Data is locally stored and synchronised with the *Central Repository* of the *PRS*. The latter sub-system sent to PMD medical treatment and communication messages from the professional. Finally, the AFMs are retrieved from the *AFM Manager* and managed by the *AFM Patient* module for visualisation and configuration setting. The AFM Patient is lastly responsible to collect all patient data and send them to the Behavioural Analysis module to be inspected.

AFMs are shown in the “Messages” menu and listed together or filtered by type, as depicted in Figure 45.

Figure 45. Overview of a List of AFMs

Behavioural Analysis Module

The *Behavioural Analysis (BA)* module is in charge of extracting information from the patient's dynamic database and assessing the patient behaviour. This task includes the analysis of patient's adherence and engagement that will lead the EBF to autonomously update the current list of AFMs in the *AFM Library*. Patient adherence and engagement are calculated from the analysis of the user inputs from the data collected from the PMD. The main modules to which the engagement and the adherence are calculated include Medication intake, Nutrition, Physical Exercise and Education. The description of the equations defined for deducing these indices is presented in Paragraph 4.1.8.

The *BA* is also responsible for estimating the patient reaction when interacting with the *PS*. In particular, the patient's feedback when receiving an AFM is monitored and analysed: behaviour assessments are based on the analysis of the interaction of the patient while using the PMD. This indicator, called *ECHO*, depends on four parameters:

1. ***AFM Reading***, calculated from the confirmation of the message from the patient;
2. ***Weekly Usage***, calculated from the analysis of usage for each module during the last week;
3. ***Weekly Treatment***, calculated from the analysis of adherence for each module during the last week;
4. ***Patient Mood***, calculated from the last mood input;

The first three parameters influence the schedule with which an AFM is sent, while information from user mood, reflects on the AFM appearance. The results are the re-calibration of four parameters, represented in the *AFM Configuration Setting* table. The table, shown in Table 5.2, contains information of how each AFM appears, that is:

- *Time scheduling*: for each topic and corresponding sub-topic, programmed inputs are foreseen according to patient medical treatment. The AFM Matching Module manages the dispatching of the AFM according to the instruction of the AFM Scheduler that control the send time and frequency of the text messages.
- *Repetition Period*: when an AFM is skipped, the system can present it again at a later stage. This value determines the time interval between the AFM and its repetition, when needed, managed by the AFM Scheduler.

- *Max Repetition Number*: maximum number of repetitions for an AFM. This value is adjusted to the *Level* of the AFM, meaning that it will be greater for warning and goals, and lower for recommendations and tips.
- *Appearance*: corresponds to how an AFM is expressed, according to the principles of the health communication guidelines and the persuasive principles. In order to cover effective verbal communication, specific protocols related to message structuring must be applied in order to optimise the patient engagement. Some of these principles include applying social influence, showing people what they could lose, link short term efforts with long term gains, put the message where the action is, use examples invoking trust authorities and offer simple and understandable guidelines. The choice an AFM is presented depending on Patient Mood, Repetition Period and Patient Profile:
 - *Patient Mood*: the influence a message may transmit to a person is linked to its behaviour. That is why, before dispatching an AFM, the system controls the moods of the current day.
 - *Repetition Period*: if a patient skips a message, it may be useful to send it again in a different way to reinforce its effectiveness. When an AFM is skipped, the *AFM Scheduler* waits for the next dispatch according to the programmed *Repetition Period*. In this circumstance, the AFM can be shown with the same content but expressed in a different way.
 - *Patient Profile*: the information gathered from the baseline visit represents the first filter to assess the user inclination on which communication may be more effective.

These parameters are pre-set during the baseline from clinical and psychologist professionals and are progressively revised from the system, based on the feedback of the user when interacting with the PMD. For instance, if a patient is tired of receiving too many messages, they will start pressing the “Skip” button when receiving a specific AFM. This action will be stored by the system and will be gradually measured to estimate the user behaviour. Thereafter a suitable solution will consist of accommodating their preferences while maintaining the AFM support, so the system will act by changing the form to express the AFM, or decreasing the maximum number of an AFM repetition. In this case, the *BA* updates the scheduling of the message with a thirty minutes’ delay and reduces the repetition of a message that was already dispatched. Regarding the form in which an AFM is conveyed, three different expressions are defined conforming to user behaviour.

Table 5.2. AFM Configuration Setting

This processes patient device interaction and biosensor data, updates patients' behavioural information in their profile and provides the *Matching* module with information related to adherence and engagement.

ID	Time Scheduling	Appearance	Repetition Period	Max Repetition Number
001	After Lunch	03 – “Please Remember to provide your insulin dose”	Every hour	2
002	Before Breakfast	02 – “Did you already measure your glycaemic level? If yes, please provide the corresponding value”	Every hour	1
004	Before Sleep	03 – “Yesterday you didn’t provide your glycaemic value before sleep, please always remember to perform this action”	Every 15 minutes	1
005	Every week	01 – “You should improve your daily steps to 15000”	Every 2 hour	3

Using the *PRST* interface, caregivers are informed on current treatment follow-up, including the AFM and scheduling the system is currently assigning to each patient. Furthermore, patients can activate/de-activate some categories of messages. For example, a patient that is tired of receiving too many recommendations on practice exercises in the morning can choose to turn off the physical activity message module, through a module in the PMD, named *AFM Configuration Setting*.

The *AFM Configuration Setting* allows the patients to manually set up the levels of AFM according to their preferences. Patient can:

- Activate/de-activate an AFM category
- Set up the scheduling
- Set up the repetition period
- Set up the Max Repetition Number
- Set up the appearance
- Set up the level

Finally, the user can choose the language to which they want to receive the AFM. Figure 46 shows two screenshots of the *AFM Configuration Setting* module.

Figure 46. Two screenshots of the AFM Configuration Setting module

The *ECHO* indicator values are processed by the *BA* and transmitted to the *Matching* module in order to update the *AFM Library*. The library can be updated by:

1. Adding a new AFM
2. Modifying an existing AFM
3. Deleting an existing AFM

These actions are executed by the *AFM Manager* under the professional supervision. An example set of pre-defined conditions, derived from the applied behavioural change theories, for supporting the professional in configuring the *AFM Manager* is shown in Table 5.3.

Table 5.3. Pre-defined condition for AFM Library update

	Insert	Delete	Edit			
			Sched uling	Appearance	Repeti- tion	Max Number
Reading			<50%	<50% + Repeti- tion >2	In- crease: <50% De- crease: > 85%	Increase: <50% Decrease: > 85%
Usage- Ad	<85%	>95%	< 50%	20% > UA > 20%	< 50%	< 50%
Treat- ment- Ad	<85%	>95%	< 50%	20% > TA > 20%	< 50%	< 50%
Mood				A, C, E, H, U		

As shown in the table, the *AFM Library* update operations can be calibrated according the levels of the Reading, treatment and usage adherences and mood.

In summary, the EBF interaction usage scenario can be described in seven actions:

- 1) Clinical, physiological and behavioural data are collected during the screening visit through laboratory and clinical tests, medical visit and behavioural test surveys.
- 2) The professional creates a new user record of the patient on the *PRST* and entry their baseline data, stored in the *Central Repository*, in the view of being pre-processed.
- 3) The professional sets medical and lifestyle prescriptions and decides what kind of input the patient needs to collect from medical sensors and through manual inputs.
- 4) Information about the care plan are sent into the AFM matching for being analysed by the EBF logic that will select the corresponding AFM library.
- 5) The patient is given the PMD and trained how to use it.

6) Based on actual patient's inputs, adherence is estimated, and feedback messages are delivered.

7) Through the tools provided by the *PRST*, the professional control the overall status of the care plane in terms of treatment and usage adherence, AFMs dispatched so far, priority of generated alerts, *ECHO* indicator, and decide if it is necessary to intervene, by adjusting the treatment or by contacting the patient to better understand his/her health status.

5.3 A solution to improve adherence in diabetes

The nature of diabetes and its effect on a patient are determined both by the features of the disease itself and the state and personality characteristics of the patient. Personalisation of treatment is the basic determining factor for a useful and successful engagement strategy to be applied in an eHealth system. The engagement strategy uses the AFM as a vehicle to improve the patient's adherence. The patient's engagement is integrated in the philosophy of the design of the system and it was taken into account during the entire interaction design process.

5.3.1 EBF implementation in the METABO system

Given the impossibility to substitute the social support around the patient via using an ICT system, a main challenge the patient's engagement faces is providing the patient with the support and information that no doctor or person around can give in daily basis while following the treatments. As a premise to design the EBF, it has been considered that the single fact that patients are using a monitoring system to track their status, implies that there is the intrinsic motivation to improve and take care of their own health, something that cannot be promoted externally by any system. Given this, the EBF stresses the improvement of treatment adherence, positive lifestyle changes and the attainment of goals set by the doctors, together with the education of patients in the disease and its consequences to avoid chronic complications.

Motivation and support for diabetic patients is desirable for the treatment of each type of diabetic patient. Since the capacity of individuals to self-manage is impacted by different factors including education, knowledge of the disease, knowledge of oneself, assumption of the condition and its consequences, and fear of making decisions related to the treatments, the EBF has been adapted to tackle all these aspects from different fronts, shaping each feature of the system to have an impact on them. Furthermore, the EBF has been designed to provide the diabetic patient

with some specific tools to enhance motivation and education as part of the treatment and self-management of the disease with the aim of improving the adherence of medical treatment in the short and the long term.

Among the main motivational tools, the EBF includes:

- Customised educational content for patients' consult.
- Helping patients understand the relation between lifestyle and health condition and how their activities positively or negatively affect their physical and health status.
- Having an effect on identified psychological factors that may prevent patients to follow the recommended guidelines for their treatment.
- Providing the patients and medical doctors with a tool to set goals and to control the process that leads to the attainment of these goals.
- Promoting the engagement of the patient in the treatment decision making process, supported through education and communication with the professional.

The EBF has been validated through its integration into the METABO system, a comprehensive monitoring platform for diabetes care. This choice was coherent with the idea that METABO was a modular solution, with specific components and tools for the different aspects and problems (of medical monitoring and control of the disease, of adherence to specific lifestyle and patients' conditions) imposed by diabetes.

The implementation phase has been carried out employing different methodologies, with the aim of gathering qualitative data to assess the EBF development requirements. Supplementary specifications were extracted from use cases analysis methods.

The segmentation of the diabetic patients allowed us to address some specific situations in which patients may develop specific needs. Not only a review of the particular user needs related to each segment was done, but also a general description of the basic features that the METABO platform provides for the six segments that are common for all the users, independent of their profile. They can be summarised as:

- Acquisition of information from glucose measurement sensors, either by using a continuous glucose monitoring system or other manual systems

- Acquisition of information related to the patient's lifestyle through interaction with a user application: food intake, drug intake, physical activity schedules
- Acquisition of information related to complications and co-morbidities interacting with the diabetic disease
- Measurement of different variables related with the patient's ongoing treatment evolution such as weight and fat
- Measurement of different variables in the environment affecting the patient's behaviour such as temperature
- Processing of all data and developing the required metabolic and behaviour models needed for prediction
- Design of a decision support system to assist in the recommendations for patients enhancing empowerment and self-assurance of diabetic patients

5.3.1.1 Description of the deployed EBF components

From a system's component point of view, the main services of the system foresee the communication between patient and doctor through two terminal applications, connected through a central server for managing data and services. The patient application allows the connection with personal health sensors as blood glucose and physical activity monitors, automatically synchronised through the platform with the professional application. The implementation of the EBF into the METABO system belongs to the patient side, professional side and the central server. The following modules have been developed:

- Patient Side:
 1. AFM Module
 2. Goal-Setting Module
- Professional Side:
 1. AFM Management Module
 2. Treatment Adherence and Usage Adherence Module
 3. Goal-Setting Management Module
- Central Server:

1. Core Engine Module

5.3.1.2 Patient Side

Based on the specification of 5.2.2.2, the architecture of the Patient Side has been implemented and deployed in the METABO system. From a development point of view, the Patient Side can be seen as an application, installed onto a mobile device, such a smartphone or a tablet. Given the nature of the proposed system, the mobile interface, in this study is called the PMD. The PMD integrates all healthcare monitoring tools needed for T1DM and T2DM treatments. Functionalities include prescription receiving, professional communication messaging, physiologic and lifestyle inputs, data visualisation interfaces, sensors and medical device connections. In order to maximise the user interface interaction, two different applications were developed, one for T1DM and one for T2DM. The T1DM application is orientated towards younger patients, in terms of personalisation and data visualisation. Whereas, the T2DM application is more accessible and orientated towards older patients and usually less inclined to self-care.

Both of the applications can be presented as an electronic diary. Patients can use it to report their daily activities and communicate with the professional caregiver. The main functionalities of the application related to reporting inputs correspond to the five dimensions defined in 0: NU, for reporting daily diet; ME, for reporting glycaemic levels, weight and blood pressure measurements; MD for medication, PA for physical activity and ED for educational content and quiz. Apart from this, the application allows for the downloading of biomedical measurements from medical devices, described in 4.2.5.

Other functionalities foresee a graphic trend view, to allow the patient to monitor their own daily/weekly and monthly progress, a message communication for chatting with the medical doctor, the AFM module for accessing messages and automatic feedback and the Goal-Setting module, for managing goals.

The PMD is connected with the professional panel through a central server, which is responsible for registration, security, authentication, data storage, synchronisation, and updating of the AFMs. Even if an Internet connection is required to receive and send data to and from the central server, the PMD can be also used whenever there is no connection available: application can run with reduced functionalities of data management and store the offline data in a temporary table of the PMD database, that will be updated whenever the Internet connection is available. The synchronisation process is transparent to the patient. A scheme showing all the functionalities the PMD offers is depicted in Figure 48.

T1DM application

The PMD interaction was designed according to the type of interactions the users have. The functionalities provided by the EBF resemble the actions that the patient is more used to performing. As anticipated, the T1DM application is easily customisable, allowing the user with a fast and easy data access, input and visualisation. For instance, a user can access the diary and graphics areas directly from the home screen and graphic tools offer complex chart visualisation.

With regard to the associated deploying technology, Windows Mobile 6.5 SDK was used to build the T1DM application. The main menu screen of the application can be observed in Figure 47.

Figure 47. T1MD application main menu

The menu displays the last input measurements and a direct link for the main modules access. In the upper side of the menu, the calendar icon allows access to the user calendar, while the underlying icon links access to AFM and the caregiver communication modules.

Figure 48. Overview of the PMD functionalities

RESULTS

Other functionalities, available from the bottom side of the menu, include the Diary, the “Education” tool, the “Graphics View” (Figure 49), the “Prescriptions” tool and “Sensors Measurements Synchronisation” tool (Figure 50) and the “Profile Setting” tool.

Figure 49. T1DM application - Graphic View

The “Mood emoticon” button, displayed in the upper section of the screen, allows the user to select their current state of mind. The main menu screen of the application for T1DM is shown in Figure 47.

Figure 50. T1DM Application – Prescriptions module (a) and Sensor Measurements Synchronisation (b)

T2DM application

T2DM application was designed to be very easy to use, with a stronger emphasis on persuasion, with special attention on the content and dispatch of the AFMs. T2DM are used by aged patients who are not insulin treated, therefore the focus for their related application is not only on data input, but on education, and empowerment to adopt a healthier lifestyle. The T2DM application was designed to be initiative, and motivate and support the user without him always asking for it. The application was developed in using the Apple iOS 4 SDK. The main menu screen of the application for T2DM is shown in Figure 51.

Figure 51. T2MD application main menu

As for the T1DM application, the treatment for T2DM consists of diet, physical exercise and medication. Since one of the main priorities for T2DM patients is the prevention of complications, the application is orientated towards health improvement, especially in reinforcing educational content and in changing patients' bad routines. The main T2DM application modules are shown in Figure 52.

Figure 52. T2DM Application – Communication (a), Medication (b) and Measurement (c) modules

AFM Manager

The *AFM manager*, integrated in the PMD, is responsible to manage the automatic messages to be dispatched into the T1DM and T2DM applications. The selection of the AFMs as part of the *AFM Library*, used to display the messages into the patient PMD, can be imagined to be defined through three distinct temporal phases. The phases involve both modules from the Professional and Patient Sides:

- Phase 1: The patient baseline data are analysed by the Patient Screening Profile module. This activity includes an assignment of a transtheoretical stage, a patient segmentation according to the type of diabetes, the study of the laboratory and clinical data, and the examination of the lifestyle activities.
- Phase 2: Based on the baseline data, the Prescription Manager module manages the treatment selection, based on both the professional and system prescription' strategies: the TTM level and the segment of patient as-signation allows the system supporting the professional in terms of pre-scriptions, in particular on:
 - Nutrition: RDK
 - Physical Activity: recommended weekly METS
 - Education: customised educational content
 - Measurements:

- Glycaemic: recommended number of glycaemic self-checks
- Blood Pressure: recommended number of blood pressure measures
- Weight: recommended number of weight measures

Based on the system suggestion, the professional completes the prescriptions, integrating other prescriptions such as anti-diabetic and insulin intakes. Then, together with the patient, the professional pre-arranges new goals to be achieved.

Phase 3: On the basis of patient behaviour, the *AFM Manager* module starts displaying the AFMs through the PMD. Once analysed by the Behavioural Analysis module, the messages are periodically updated in the short and the long term periods, depending on: patient behaviour, changes in the overall treatment and, less often, new patient baseline screening.

Figure 53 shows a scheme that illustrates the three phases for the AFM generation.

Figure 53. Scheme illustrating the three phases for the AFM generation

According to AFM definition in 5.2.1, four levels of AFMs were defined. When dispatched, the AFMs are shown as pop-ups displayed on the PMD. Message icons are displayed in different colours, according to the severity of each: warnings were identified in red, reminders in yellow, tips and goals in green (Figure 54).

Figure 54. List of a) Warnings, b) Reminders and c) Tips, in the PMD

Scheduling of AFM

The AFM Scheduler manages the logic behind the AFM's dispatch by use of transmission synchronisation methods. AFM transmission can be synchronous if the message logic is synchronised by an external clock, while transmission can be asynchronous if the message logic is synchronised by a special event along the transmission medium. Specifically, if an AFM is related to an un-predetermined or regular interval, the dispatch of the message is asynchronous. This condition is referred to as a Short Term (ST) AFM. Short term AFMs are commonly associated to an unexpected event, for instance, a missing input of a prescription during the last 24 hours.

When the missing data input is notified through an AFM, the patient can decide to skip the notification or inform the system. Figure 55 shows the use case of a ST AFM related to the nutritional treatment, where the patient is notified of not correctly following the dietary recommendations.

Figure 55. Nutrition Short Term AFM

The synchronous message dispatch is based on events: an event corresponds to a particular period of time and the AFMs are scheduled to be triggered according to a corresponding, associated event. Once the caregiver adds a new prescription, the corresponding AFMs are transferred from the central database to the PMD local database. The AFM Scheduler automatically associates the warnings to the prescription events. For example, in case of a medication intake, as soon as the medical drug is prescribed, it will be associated to a temporal event, which is that the patient is required to take it during the event assigned to that drug. When a drug is prescribed, the system knows what the usual time is for that patient, according to its preferences. So, in the case where a drug is prescribed to be taken before breakfast that is scheduled between 09:00am and 10:00am, a message will be triggered fifteen minutes after the time period. As long as the patient inserts the requested information, another pop-up message will appear to remind them to react. The system logic is configured on a certain time repetition period and a maximum number of repetitions. The nutrition warning message is shown in Figure 56.

Figure 56. Warning AFM

If an AFM is related to a predetermined or regular interval, the dispatch of the message is synchronous. This condition is referred to as a Long Term (LT) AFM. Long term AFMs are commonly associated to low levels of adherence calculated over one or more days. Figure 57 shows a LT AFM related to the nutritional treatment, where a patient is notified for not correctly following the diet recommendations in the last week.

Figure 57. Nutrition Long Term AFM

Four examples of AFM use cases are available in Appendix IX.

Transtheoretical Stage of Change

In order to assess a diabetic patient stage of change and guide the patient through a personalised care plan, the target behaviour and the desired final behavioural goal are pre-set for each patient. The TTM, in fact, does not specify how much time is needed for each stage, or how long a patient can remain in a stage. Usually the achievement of a new stage is determined based on clinical evidence on the level of the behaviour necessary to obtain proper health benefits. For this reason, the stage of changes is set depending on the patient's initial behaviour and the personal medical history, gathered from the screening process. Progressively, when a care plan starts, the stage of changes may change, according to the quality of the patient's behaviour and treatment evolution.

Since each stage of change is specific to a different behaviour, appropriate motivational strategies for the caregiver are adopted accordingly. This includes the assignment of a specific set of AFMs with the aim to persuade the patient through a tailored intervention. A summary of the strategy adopted by the framework based on the patient's treatment needs to each stage of change is shown in Table 5.4.

Table 5.4. Stage of Change - EBF Strategy

Stage of Change	Treatment Needs	EBF Strategy
Pre-contemplation: patients reported no intention to change their behaviour in the foreseeable future	1- Improve readiness 2-Encourage re-evaluation of current behaviour	1-Tips: Educational content on diabetes risks and benefits from healthy lifestyle and suitable diabetes treatment

Contemplation: patients are not prepared to take action at present, but they are intending to, within the next few months	1-Define long-term maintenance plans 2- Improve readiness 3-Encourage re-evaluation of current behaviour	1-Tips: Educational content on diabetes risks and benefits from healthy lifestyle and suitable diabetes treatment, foster caregiver communication, information on correct diet, physical activities benefits, medication intakes
Preparation: patients are considering changing their behaviour in the immediate future	1-Establish new goals and strategies for change together with the patient 2-Offer personalised advices 3-Verify patient skills for behavioural change	1-Educational Goal 2-Tips: Educational content on diabetes, foster caregiver communication, nutrition, self-check measurement, physical activities benefits, medication intake
Action: Patients have actually made an overt behaviour change on their care plan's adherence in the recent past, but the changes are not well established	1-Engage patients in treatment and reinforce the importance of remaining in recovery 2-Help the client identify high-risk situations 3-Assist patients in finding new reinforces of positive change	1-Education Goal (quiz topics will be customised on patient clinical profile) 2-Weight Goal (if needed) 3-Tips: Educational content on diabetes, foster caregiver communication, nutrition, self-check measurement, increase physical activities, medication intake 4-Medical Panel: Maintain a constant patient-caregiver communication
Maintenance: patients have a good care plan adherence control and they are working to sustain their behaviour	1-Support patients with relapse prevention	1-Educational Goal (relapse prevention contents) 2- Tips: Maintain supportive contact with caregiver 3-New Goals (i.e. Improve Physical Activity)

In addition to this, the professional will adjust the patient's current stage individually and according to his/her preferences.

Health Communication

As described in Chapter 4, communication design paradigms were used to lead to the definition of the AFM. The health communication principles were applied on the EBF as following:

- **Remind patient of what they want to achieve:** Educational contents and Tips are customised on patients' clinical status, adherence, stage of change and assigned goals.
- **Applying social influence:** Customised tips on social influence are provided.
- **Showing people what they could lose:** Educational content, Reminders and Tips messages focusing on diabetes risk and complications.
- **Link short term efforts with long term gains:** Educational content, customised tips on short and long term objectives.
- **Time appropriate messaging:** Events for the AFM synchronous triggers properly set on patient treatment prescription time scheduling.
- **Provide an objective:** Provided within the action plan of the Goal messages.
- **Invoking trust authorities:** Specific Tips messages and educational content refer to best practices from WHO and AHA.
- **Positive or gain-framed:** Apart from the Warning messages that need to alert the patient, all Reminders, Tips and Goals are expressed positively.
- **Simple content, never mixing different kinds of information:** all AFMs content is clear and synthetic, particularly in the Warning messages.
- **Never too many:** AFMs are adapted according to patient preference. Max repetition number is also limited to patient needs.

Technology Persuasion Principles

Principles of persuasive technologies have been applied in the EBF. In particular, the type of AFM, the delivery time and the maximum repetition number are depending on the patient daily attitude and daily state of mind, as following:

- Daily attitude:
 - If a Reminder is skipped, the second Reminder pop-up will include a link button of the educational content related to that Reminder
 - After a Reminder has been sent twice, a Warning message is sent.
- *Daily state of mind:*
 - The state of mind has been limited to three moods: happy, sad, normal. If the last 24 hours' mood record is good, no AFM restriction is set. If the mood is normal, frequency of messages is delayed by 30 minutes and the maximum repetition number is decreased to one unit.

Goal setting intervention

Goals are agreements between professionals and patients regarding achieving specific objectives related to the medical treatment. Within the METABO platform the Goal-Setting Theory of Motivation has been applied in two of the sub-modules of the EBF, as a target to achieve a behaviour or a physiological value in losing weight and improving educational knowledge. Goals can be assigned through the Medical Panel and then synchronised on the EBF. A specific Goal sub-module allows the user to show the evolution and the current objective's status, previously agreed with the doctor.

It is important to stress that there is not only a final goal to be accomplished, but the aim is the process to be followed to achieve it itself. Hence, it becomes crucial to evaluate the behaviour of the patient during the whole period of time and to distinguish whether they are following the set protocol or not. Otherwise the activity could become counterproductive, i.e. if a patient is reducing their insulin intake to lose weight instead of controlling CHO intake.

These activities are often a “target” to trigger a change in the patients' lifestyle and that is why they are also an engagement factor in the shape of a challenge. Goals must be tailored to the patients' capabilities and conditions by the professional and the corresponding options should be set to allow the system to keep track of the patients' progress.

During the whole process, the EBF sent the AFMs to the patients through their PMD, as well as informing the professional on the current goal status. The messages content and scheduling of the Goal-Setting Module have been defined following the principle of the GST. These principles include the following statements:

- Patients only receive positive feedback once a goal is achieved. Not only is the final goal taken into account, but also the achievement of each single target as the positive progress of the patient. As an example, if a patient drops 500gr a week following a plan that considers 4kg loss as a final goal and an average of 300-600gr loss per week during 8 weeks.
- A report is sent to the physician in case there is not positive progress from the patient and goals should be revised
- Patients should not receive negative feedback about their performance directly from the EBF, but only through their caregivers through a personalised message through the system or during the visit. For instance, if the same patient did not lose weight in one month and gained one kilogram during the second one.

The physician must be able to define a personalised treatment through the Goal-Setting designer tool from the Medical Panel, by specifying those small steps that constitute the middle term targets.

During the whole process, the system keeps track of the steps followed by the patient and provides feedback through AFMs with level 4, constituted by customised warning, reminders and tips messages.

5.3.1.3 The Medical Panel

The Medical Panel (MP) is a web-based application that physicians' access through the internet. The system is designed to be user-friendly and to optimise the caregiver's job, facilitating the search of information and the communication with patients. The MP allows the professionals performing classification and triage, structuring the clinical processes, analysing meaningful presentation of aggregated data, and prescribe treatments that are based on therapy, education, lifestyle, goals and recommendations. The MP addresses the medical treatment in line with the five dimensions of prescriptions (NU, MS, PA, ED, MD). Moreover, a dedicated section of the MP provides the doctors with functionalities for controlling the patient behaviour in terms of: AFMs received, PMD usage, treatment adherence levels and goal-setting functionalities.

The MP integrates the professional side modules of EBF: a module for AFM management, a module for controlling patient's treatment adherence and usage adherence and a module for setting and controlling the patient's assigned goals.

The main menu, depicted in Figure 58, shows the list of patients, named Patient Records, an agenda with the caregiver's main appointments and a window to indicate the number of AFM-warnings that patients have received in the last week. Apart from the patient's general profile information, the Patient Records panel include:

- Automatic Feedback Messages: Number of AFMs received in the last 24 hours by patients
- Unread AFM: Number of AFMs patients have received but not still read

Figure 58. MP - Main Menu

The menu allows the caregiver creating new instances of patients and entering into the pre-created patients' treatments. Based on the 2008 American Diabetes Association (ADA) Guidelines (Care 2008), five different milestones in a patient's treatment workflow were identified. Although the guidelines are focused on T2DM, they were generalised to serve as a framework for T1DM as well:

1. Diagnostic: following a caregiver's request, the patient has the first contact with an anti-diabetic ambulatory. He undergoes to examinations and laboratory tests. Based on them, the professional makes the final diagnosis.
2. Educative: according to a patient's lifestyle, medical staff teach the patient how to deal with glucose level maintenance, physical activity, nutrition, medication, complications and the importance of regular reviews.
3. Treatment management: patients are requested to manage their disease through food intake, drug intake, glycaemic levels and physical activity.

4. Complication risk management: in order to prevent complications, or if already diagnosed, specialist visits (i.e.: ophthalmologic, cardiologic, podiatrist, etc.) are planned.
5. Maintenance phase: this is the routine pathway for diabetic patient follow up. The professional can request medical advices and modify the treatment. Visits are planned according to the clinical situation evolution.

Once a patient has been selected from the main menu, the first screen, named Patient Data & Tools panel, provides information about the patient general status such as complications events, past visits, upcoming appointments and recommendations provided by the system. Moreover, the “Patient Data & Tools” panel integrates part of the *AFM Management* functionalities through a dedicated panel, which allows the caregiver to visualise the AFM (Figure 59). These messages correspond to the AFM received from the patient.

Created	Type	Message	Ack date	Event
23/02/2012	Warnings	Your before-meal glycaemic level should be higher. If this happens	23/02/2012	Glycaemia
22/02/2012	Reminders	During the last week you have not done enough exercise. Try to return	07/03/2012	Activity
		During the last week you have not done enough exercise. Try to return to prescribed duration and intensity of activities recommended to you.		
22/02/2012	Tips	If you suffer from any foot diseases, check your feet carefully after	07/03/2012	Motivational_Physical
22/02/2012	Reminders	Would you like to play the Quiz? It is a fun way to learn and it would	07/03/2012	Quiz

Figure 59. Medical Panel - AFM visualisation

The caregiver can check if the patient has read the AFM or a chat message and, if needed, disable the patient sending chat messages, for instance in case of unavailability. Furthermore, the “Messages” sub-section shows the chat messages between doctor and patient.

In the upper side of the interface, a glycaemic status panel indicates the number of hypoglycaemic and hyperglycaemic events occurred in the last week.

3 - HYPOGLYCAEMIC EVENTS OCCURRED DURING THE WEEK! (1 sensor, 2 manual)

6 - HYPERGLYCAEMIC EVENTS OCCURRED DURING THE WEEK! (2 sensor, 4 manual)

Figure 60. Medical Panel - Glycaemic Status panel

The “Patient Lifestyle” section is dedicated to manage the patient information related to the lifestyle habits (Figure 61).

Scenario Selection

☐ Sudden Hypoglycemic Events
 ☐ Unstable Diabetes Control
 ☐ Physical Activity

☐ Comorbidities Disease Management
 ☒ Changes in the Environment
 ☒ Lack of Motivation

Lifestyle Info

Patient often travelling for work

☒ Patients with working shift
 Average number of travel longer than 2 days per m...
 Average change of time zone for travel (h)
☐ Barriers to follow a standard diet (i.e. ethnical food)
☒ High variability in breakfast, lunch and dinner time

Patient performing sport

Average Frequency (days per week)
 Average Duration time (minutes per session)
 Average Intensity (METs per session)

Lifestyle Info

☒ Smoking
 Cigarettes (amount per day)
 Smoking since
☐ Hard drugs and opiates status
☐ Alcoholic intake
 Alcoholic intake (units per day)
 Alcoholic intake since

Patient affected by following diseases

☐ Liver failure
☐ Stroke
☐ Infarction
☒ Renal Failure

SAVE

Caption

Recommended by METABO due to patient data
 Data introduced via PMD

Figure 61. Medical Panel - Patient lifestyle

Based on the information retrieved from the patient screening, the caregiver assigns the patient to a scenario, following the system suggestion. Then the caregiver updates other information on the patient's lifestyle. The data includes the number of trips per month, the physical exercises weekly frequencies, which can be compared with the real data, and drinking/smoking habits.

The "Educational Messages" tab allows the professional to select the diabetes educational content, from a list of topics, to be forwarded to the patient in order to improve their knowledge (Figure 62). The assigned topics are suggested from the system through an icon located next to the corresponding topic. After educational topics are selected and sent to the patient's PMD, the "Quiz" tool is available to be used.

RESULTS

Figure 62. Medical Panel - Educational Messages

The quizzes are composed using questions related to the topics assigned to the patient, using a library of questions for each topic, sorted into three levels (Beginner, Intermediate and Advanced). Each quiz contains nine questions, all at the same level. The default level is Beginner. If the user successfully completes four consecutive quizzes with correct responses of more than 80% of the questions, the level increases. If more than two consecutive quizzes have a score of less than 40%, or if the educational module has not been used in the course of the last month, the level decreases. The third tab is composed of two sections: the first one allows the carer assigning and monitoring patient clinical and lifestyle data through graphical view and tables (Figure 63).

Figure 63. Medical Panel – Treatment Management tab

A dedicated sub-section shows information on patient treatment adherence and system usage, based on 0 indices, as shown in Figure 64.

Application Usage and Treatment Adherence: General Overview			
Start Date	15/10/2012	End Date	15/12/2012
SHOW			
Prescription	% of Usage	% of Adherence	Most frequent event
FOOD INTAKE	86 %	80 %	Eat adequate amount of CHO according to the quantity of administered insulin
GLYCAEMIC SELF CHECK	85 %	90 %	Your before meal glycaemic level should be lower
ANTIDIABETIC TREATMENT	82 %	92 %	Regularly taking your medication stabilizes your condition
PHYSICAL ACTIVITY	65 %	75 %	You should follow correctly your physical activity prescription, please revise your physical activity graphic tool and your related physical activity
EDUCATION	80 %	95 %	Remember to improve your education; do you want to make a new quiz now?

Figure 64. Medical Panel - Usage and Adherence View

The caregiver selects the start and end dates for which to calculate the usage and adherences indices. After pressing the Show button, the system chooses the corresponding indices for food intake, glycaemic self-check, anti-diabetic treatment, physical activity and education.

In the second part, the doctor prescribes the treatment. The first treatment section is related to prescribing the number and the daily intervals for glycaemic self-checks Figure 65.

Figure 65. Medical Panel - Glucose Monitoring

The glucose self-checks prescription can be set on a weekly basis, during the working/not working days or on a daily basis. The selection for this prescription is supported by system suggestions, based on time preferences selected during the screening process.

The second and third prescription sections are employed for prescribing anti-diabetic (Figure 66) and insulin drugs.

RESULTS

WEEKLY PRESCRIPTION

	Insulin	UI	OAD	Q
BREAKFAST	Before ☒ NOVORAPID - Flex Pen	5	Before ☒ COMPETACT - Comprimidos - 15/850 - mg	5
	After ☒		After ☒	
LUNCH	Before ☒ NOVORAPID - Flex Pen	6	Before ☒ EXENATIDE - Vial - 10 - ug	3
	After ☒		After ☒	
DINNER	Before ☒ NOVORAPID - Flex Pen	3	Before ☒	
	After ☒		After ☒	
BEDTIME	LANTUS - Solostar	30		
EXTRA TIME				

Figure 66. Medical Panel - Antidiabetic Treatment

When prescribed, a medical drug is associated to a daily event. Eight events have been defined:

1. Before breakfast
2. After breakfast
3. Before lunch
4. After lunch
5. Before dinner
6. After dinner
7. Bed-time
8. Extra-time

Drugs are prescribed before and/or after an event.

The next prescription section is used by the nutritionist to define the diet plan that the patient will have to follow. The panel allows the professional to prepare, for each daily meal, a set of courses, selected in terms of Kilocalories or CHO (Figure 67).

Define standard meals for your patient

Open Existing...

Meal Name: Breakfast ☒

Food	~ Weight (g.)
Pan de de trigo y centeno	18
Leche de vaca desnatada UHT	92
Aceite vegetal de oliva	6
Fresas	85

Save Total Kc 345

Add Ingredient

1. Select Level0 Bread and similars ☒

Select Level1 Bread ☒

Select Level2 Packaged white ☒

2. Select amount of Kc

3. Add to the meal

Set RDC target value

RDC Value: 1700.0

SAVE

Figure 67. Medical Panel - Food Intake

The nutritionist can assign a dietary plan with a RDK target value that patient should not exceed.

The Physical Exercise section is used to the set the patient physical activity.

Add Physical Exercise

1. Select intensity (METs): 1-2.9 (Light)

2. Select duration: 60 minutes

3. Select days:

☒ Monday ☐ Tuesday ☒ Wednesday

☐ Thursday ☐ Friday ☒ Saturday

☐ Sunday

4. Save

Figure 68. Medical Panel - Physical Exercise

Exercise is selected according to the METs intensity, the time duration and the number of days.

Last prescription is related to the Goal setting and it is described later.

5.3.1.4 The Central Server

The central server, also named Core Engine, is responsible to retrieve and manage the data exchanged between the T1DM and T2DM patient PMDs and the Medical Panel. A communication infrastructure, based on an Answer-Response protocol, manages the communication flow, carried out through web services invocation, between the patient and caregiver systems and the central database. Security features are designed to ensure the communication channel between the systems. All

web services are offered in a Secure Socket Layer (SSL): the system implements this security feature encrypting the information exchanged between end points. Only certified PMDs connections will be accepted by the server. A general overview of the whole platform is represented in Figure 69.

Figure 69. METABO architecture

The data model representing the AFM to be stored in the central and local databases consists of a set of tables, defined and implemented in Microsoft SQL Server Compact 3.5. The logical schema of the AFM database storage is shown in Figure 70.

Figure 70. Logical schema: AFM tables

Other relevant database tables are the “Msg_ID” that stores all AFMs with heading and text, the “Message_Types”, responsible to store the level of AFM (L1, L2, L3 and L4).

Figure 71. Logical schema: Drugs tables (client-side)

The L1 and L4 messages are generated locally whereas L2, L3 messages are generated in a central server and then sent and stored in the PMD. This choice is due to the necessity of ensuring the dispatch of the priority messages, warnings and goals, when the Internet connection is not available. Part of the *AFM Manager* is located in the Professional side and when the connection is unable, it stores the reminders and the tips in the central database. As soon as the connection is available, messages are transferred into the *EBF Repository* of the PMD. Figure 72 depicts the logical schema of the L2 and L3 messages, managed in the *Central Repository*, located in the central server.

Figure 72. L2 and L3 AFM tables

The table “MessagesGenerated” is responsible for storing the L2 and L3 AFMs generated in the *Central Repository* and *EBF database*, which have been generated at the PMD. It includes a column that indicates whether the recipient patient has acknowledged the message. The table “Message_Types” is responsible for storing

the information of AFM level. The table “Patient” records the patient identification information.

As example, the intervention of EBF in L1 warnings for Hypoglycaemic and Hyperglycaemic events is illustrated here. A L1 warning is generated when the glucose level of a patient falls out of the range of values set by the professional. For pre-set range values, the triggering conditions for the AFMs are associated to hypo/hyperglycaemic events. When this happens, the system sends a message during the day and recommends that the patient check their glycaemic level again. Moreover, the system can dispatch tip recommendations related to the event, for example eating some food when a hypoglycaemic event occurs. The Warning AFM implementation were based on timers that are activated on data input. Once activated, the timers check the triggering conditions and, if a trigger condition is verified, then the appropriate message is selected and dispatched.

Level 2 and Level 3 AFMs are managed on the Central Server and are sent to the PDM local database. When stored locally, the messages are accessible via the “Messages” table. As the L2 and L3 messages are created, the *AFM manager* module activates a timestamp, in order to measure the data evaluation period. The triggering of the L2 and L3 messages are managed by the *Scheduler* module running in the *Central Repository*. As example, the intervention of EBF in L2 reminders for glycaemic measurement is illustrated here. Once the scheduling conditions are set and activated, the AFM manager controls the patient glycaemic inputs on a weekly basis from the local database. An AFM is dispatched when a patient is not following the prescriptions in terms of treatment during a long period. For instance, an AFM is generated if the frequency of the glucose measurements is not pertinent to the corresponding prescription. In case the patient does not improve the adherence on the treatment, the *AFM manager* will stop sending weekly messages and start sending high frequency warnings.

The AFMs are dispatched on a scheduled basis. Warnings are more related to short term period messages, while reminders and tips are related to long term messages. Goal AFMs are related to both short and long term messages. For L2 and L3 messages, the period of evaluation is defined in terms of days.

5.3.1.5 Goal-Setting Module

Using the Medical Panel, the professional is able to set new goals to patients. Alternatively, professional can edit or delete a pre-defined Goal. The Goal module in the PMD periodically checks for incoming new goals. In case of a new goal, the EBF shows a pop-up message on the screen. Patients can decide to accept or reject the proposed challenge. If pre-existing goal objectives are modified, a pop-up informs

the patient regarding the corresponding update. The Goal-Setting module allows setting goals related to three types of treatment: nutrition, physical activity and educational knowledge. When setting a new goal, beginning and final dates and intermediate dates for the targets must be specified. Figure 73 shows the prescription section related to the assignment of a goal.

Figure 73. Medical Panel - Assignment of a new Goal

The image shows two goals have been set:

- **Improving knowledge:** the patient has to improve the educational knowledge from the Beginner to the Advanced level before the assigned End Date.
- **Losing weight:** the patient decides to lose his/her own weight, passing from a starting weight value to a goal weight value, within a period of time.

When a goal requested is confirmed by the user, a panel with the description of the goal is shown with a set of associated advices (Figure 74).

(a) (b)
Figure 74. Goal description (a) and Goal Advices (b)

Once entered in the goal sub-module, three sections are presented:

- **My Goal:** here the patient can check the current goal's status. Each goal sub-section contains a descriptive and graph views of the goal and an educational topic list related to the goal. Descriptive view includes generic information such as beginning and ending dates and current status. The graph view shows a two plots screen, one depicting the ideal plot to be followed and the other showing the real evolution.
- **Goals History:** In this sub-section patients can check the historic record of the attained goals. Specifically, a list including the last goals the user has completed so far, matched with a medal for each achieved goal in gold, silver, bronze:
 - Bronze medal: patient was not able to reach the assigned goal. This condition is verified when the outcomes of goal compliance reached by the patient are lower than 60% of the assigned goal.
 - Silver medal: assigned when patient was close to reach the goal. This condition is verified when the outcomes of goal compliance reached by the patient are higher than 50% and lower than 85% of the assigned goal.
 - Gold medal represents patients completed the goal successfully. This condition is verified when the outcomes of goal compliance reached by the patient are higher than 85% of the assigned goal.
- **How To:** this sub-section contains general information of the assigned goal. In particular, a set of guidelines to follow for achieving the proposed goal.

(a)

(b)

(c)

Figure 75. My Goal and Goal History sections

5.3.1.6 Educational Goal

The Education Goal aims at improving the knowledge of a patient about diabetes disease and related treatment information. The goal consists of completing quizzes in order to improve their own score level. The knowledge material is based on the educational topics prescribed by the caregiver. The choice of the topics' arguments is customised to patients. For each topic, a group of questions, sorted by difficulty level, are assigned for the quizzes. Questions are categorised according to the topic argument and by the difficulty level: beginner, intermediate and advanced.

The quizzes are based on ten questions randomly selected from the table "Quiz Table" of the database. After a quiz is completed, a pop-up will show the corresponding result and the actual patient's educational level. Patient's level will automatically increase, starting from the level Beginner, then intermediate and finally advanced. Four consecutive quizzes with a minimum of 80% of correct answers increase the level from Beginner to Intermediate. Five consecutive quizzes with a minimum of 80% of correct answers increase the level from Intermediate to Advanced. Two consecutive quizzes with less than 50% of correct answers decrease the level. Examples of quiz questions and result of quiz screenshot representations are shown in Figure 76.

Figure 76. Quiz questions and results during an Educational Goal

AFM-goals are displayed on a daily basis to encourage the patient on reaching the goal. If the patient does not perform any goal activity during a period of time, the level automatically decreases. The caregiver can check the current goal status, looking at how many quizzes the patient has completed so far as the corresponding score. Each time the professional sends a quiz to a patient, a counter indicates the number of quizzes that patient has received.

5.3.1.7 Weight Goal

The Weight Goal aims at persuading the patient to lose weight. Once the goal is set, the system focus on:

- Improving nutrition adherence through a specific set of AFMs
- Offer the patient specific and personalised nutrition educational content

The caregiver checks the current goal status from the patient weight measurement inputs and nutritional inputs. The patient is able to see the main information of their current weight goal, such as:

- Goal objective: the amount of body weight to lose in a period of time;
- Goal's period: starting and end date;
- Days left: a box showing the remaining period of time up until the end of the goal;
- Weight lost so far: the actual amount of weight lost since the goal started;
- Weight to lose: the weight that the patient has yet to lose;

Figure 77 shows a screenshot of the main goal description menu and two views of the graphic trends. As for the Educational Goal, trends view is based on a Cartesian co-ordinate system, showing the time and the weight measures. A green line indicates the ideal evolution of the body weight evaluation, while a white curve shows the patient evolution. Other information includes a kilocalories graphic flow, which indicates the caloric deficit lost by the patient in a period of time, derived from the food intake information.

Figure 77. Weight Goal - Goal description and graphic trend

Chapter 6

Evaluation of the Engagement Behavioural Framework

6.1 Evaluation of the technological framework

The technological framework validation was conducted within the R&D METABO project (METABO 2008). The evaluation aimed to assess the effectiveness of the proposed framework. The EBF was tested with usability engineering strategies that consisted of a focus group with real users, to further validate the concept and to answer specific questions that came up during the heuristic design approach. Medical Panel interaction was also tested by professionals through the realisation of usability tests, to check if the system was sufficiently usable.

After this phase, the EBF was tested in a randomised controlled pilot. The study was a multi-centre, multi-national, open-label, randomised, two-parallel-group exploratory study comparing the continuous use of EBF vs. standard care without the use of EBF. Patients that were randomly selected for the intervention group were instructed on how to use the PMD and how to achieve the recommended goals and used it for five continuous weeks. Patients randomly assigned to the Control group were treated and monitored following standard practice. The trial aimed to examine the extent to which the usage of the EBF during five weeks could be associated with a trend for improvement in the medical adherence in terms of glycaemic control and quality of life, compared to the control group. Other objectives included examining the feasibility and acceptance of the system by both patients and professionals.

Participants were recruited from four different clinical centres in Europe: Hospital San Carlos of Madrid (Spain), AUSL of Modena (Italy), Hospital of Prague (Czech Republic), and Hospital of Parma (Italy). The baseline assessment included demographics, diabetes status, profile information, knowledge about diabetes in general, usage of ICT platforms, opinion and experience about electronic devices, appraisal over the co-existence, adoption of good practices with diabetes.

The validation method used for the analysis of the framework had two main objectives to assess the effectiveness of the used framework in terms of adherence treatment and user engagement.

These objectives were achieved following these procedures:

1. Qualitative analysis
2. Quantitative analysis
3. Comparison of the results

6.1.1 EBF - Concept Definition

The main steps that lead to the EBF concept definition were meetings with diabetes experts and contact with diabetic patients. A final workshop closing this phase was held with the medical team to define the strategies the EBF had to adopt within each user's applications (Diego Ardigó et al 2012). The following modules of the patients' application in the PMD for T1DM and T2DM were discussed.

- Objectives
- What was expected from the application
- What was required from the users
- Outputs for different factors
- Features already defined
- Features yet to be defined
- Definition of sub modules

The results of the meeting defined every module of the application and an understanding of how to integrate the EBF intervention on each module and on the clinical interface.

These concepts did not take into account user interaction aspects of the application at first, but they were an initial approach to the definition of the functionalities that had to be provided to the users and a proposal to structure all the information that would be asked, shown and stored. Given the complexity and the large amount of data that would be managed by the application, the organisation of the modules and the creation of a first structure were key to be able to work in the user interaction later.

The application was defined as a modular set of features in such a way that each of them could work as a stand-alone product, allowing the complete personal choice of the modules that should be used by each patient.

In order to further the developments and the definition of an interaction design, a meeting with patients was prepared to gather their insights on the concepts and determine what their user demands and needs were regarding interaction. For this, interviews with 10 diabetic patients were held. The interview structure was as follows:

1. Introductory talk
 1. Patient profile data
 2. Patient lifestyle data
 3. Survey 1: Generic questions on patient background
2. Insights Validation: Major problems related to diabetes
 1. Monitoring: Nutrition, Physical Activity, Measurements, Medication, Education
 2. Feedback of the care plan
 3. Alerts and Simulation for Re-assurance
 4. Communication with the doctors
 5. Survey 2: Questions on patient insights
3. Presentation concepts
 1. Introduction to the system
 2. Introduction to the EBF
4. Concepts Validation
 1. Survey 3: Patient validation of concepts

From these interviews we found important answers to key questions to proceed with the refinement of the concept framework and to continue with the development process.

6.1.2 EBF software version used during the trial

The EBF used for the experimentation presented some limitations with respect to the proposed defined architecture. In particular, due to the missing of a complete version, the limited period of weeks available and the necessity to dispose of a robust software version, the following adaptations have been carried out:

- ECHO: the ECHO was calculated from the AFM reading, mood information tool was not integrated
- TTM level: the stage of change was fixed to each patient and limited to three levels (3, 4, 5)
- AFM level: the level of AFM was fixed, so that each AFM content was associated to the same level
- AFM library: the *AFM Library* update has been implemented manually

6.1.3 Study Patients and Professionals

Fifty-one out of 54 patients, who were enrolled, completed the trials. Twenty-six patients were assigned to the intervention group and equipped with the PMDs: 14

patients were T1DM and 12 were T2DM. The control group was composed of 25 patients who were treated with standard care, without the usage of the EBF system. 15 patients were T1DM and 10 were T2DM. Table 6.1 shows how the 51 patients were assigned in the study.

Table 6.1. Total patient's disposition

DISPOSITION OF PATIENTS	T1DM		T2DM	
Gender	Intervention	Control	Intervention	Control
<i>Males</i>	10	9	9	8
<i>Females</i>	4	6	3	2

Patients were on average of normal or slightly overweight, with a long history of disease and relatively acceptable glucose control. The patients' profile information is shown in Table 6.2.

Table 6.2. Patient profile information

Variable	Men (N=36)	Women (N=15)	All (N=51)
<i>Age</i>	49 ± 12	42 ± 11	48 ± 12
<i>BMI at baseline</i>	26,3 ± 3,7	23,3 ± 3,9	25,7 ± 3,9
<i>Body weight at baseline</i>	81,2 ± 17,4	63,8 ± 10,8	77,6 ± 17,6
<i>Body weight at end of study</i>	80,8 ± 17,2	63,8 ± 10,4	77,3 ± 17,4
<i>Type of diabetes</i>			
- T1DM	19	10	29
- T2DM	17	5	22
<i>Duration of diabetes**</i>	20(13)	17(14)	20(13)
<i>HbA1c at baseline*</i>	7,8 ± 0,9	8,1 ± 0,9	7,9 ± 0,9
<i>HbA1c at end of study</i>	7,6 ± 0,9	7,7 ± 0,8	7,6 ± 0,8

Footnote: data are expressed as mean ± SD. * data expressed as number of cases; ** age of disease diagnosis. Data expressed as median (interquartile range)

Two baselines were prepared at the beginning and at the end of the trial. All screened patients who fulfilled inclusion and exclusion criteria entered the first baseline for at least 3 days. Baselines consisted in retrieving patient personal profile data such as: clinical data, demographic data, diabetes history, diabetes complications, past medical history, physical examination and laboratory data. All patients were instructed on how to record physical activity, through the combined use of a pedometer and a wearable metabolic Holter device called Armband, and their manual glycaemic inputs with a portable glucometer. T1DM were also instructed on how to record the continuous subcutaneous glucose concentration by the CGMS. At the end of the first baseline period, patients were assigned to the two treatment groups, either intervention or control. The intervention group was instructed to the use of the PMD and were provided with the PMD and a desktop device for sensor management when the patients were at home. The control group were asked to record their data in a written, paper diary.

Inclusion criteria for the trial were:

- Written informed consent before undergoing any study-related procedure
- Both genders, age ≥ 18 years
- T1DM or T2DM diagnosed following ADA criteria
- BMI < 35 kg/m²
- HbA1c $< 9\%$ (based on the latest available laboratory exams within the last 6 months)
- Absence of significant micro- and macro-vascular complications
- Capacity to understand study procedures and the use of a handheld device (PMD)
- High level of compliance with investigator's instructions (as judged by the investigators)

Exclusion criteria include gestational diabetes and severe, chronic concomitant diseases that are invalidating or life-threatening.

Professional's intervention for both intervention and control groups was carried out by 24 care providers, including endocrinologists, nutritionists and nurses. Professionals were provided with the Medical Panel application, installed in a desktop device.

6.2 Assessment of the results associated to the EBF

The analysis of the study comes from the results of the surveys answered by both professionals and patients during baseline 1 (B1), baseline 2 (B2) and from the analysis of data during the first half (Phase 1) and the second half (Phase 2) of the trial. System acceptability and user satisfaction were measured through the LimeSurvey online multi-language survey. Other outcomes were retrieved from the analyses of the log-files from patient and professional applications. Finally, a considerable amount of data was gathered from the local PMD database and from the *Central Repository*.

The assessment of the study outcomes associated to the EBF are based on the following:

- Measurement of the care plan's adherence of patients in terms of treatment adherence and usage adherence;
- Measurement of the perceived usefulness of the overall system for patients and professionals
- Measurement of the perceived usefulness of the EBF for patients and professionals
- Measurement of the appraisal of diabetes
- Measurement of the adoption of good practices
- Measurement of the system attractiveness

The list of surveys that patients completed during baseline determination are shown in Table 6.3.

Table 6.3. List of patient surveys

	Intervention group		Control Group	
	B1	B2	B1	B2
<i>General info quiz</i>	X	X	X	X
<i>Appraisal of Diabetic scale</i>	X	X	X	X
<i>Adoption of Good Practices</i>	X	X	X	X
<i>AttrakDiff</i>		X		
<i>Perceived Usefulness</i>		X		
<i>EBF Perceived Usefulness</i>		X		

The list of surveys for the professionals consisted of:

- Measurement of the perceived usefulness of the EBF

With respect to safety assessment issues, no major safety issues arose during the study. For patients who withdrew for whatever reason, an adverse event form was prepared with an explanation for the reason of discontinuation.

6.2.1 Patient ICT experience

The usage of the smartphone for the intervention group was measured in terms of hours per week and data packs sent, represented in megabyte (Mb) sent and the experience of the intervention group was measured.

The usage of T1DM and T2DM applications, in terms of hours per week, is shown in Figure 78.

Figure 78. Intervention group usage – Hours per Week

The usage of T1DM and T2DM applications, in terms of data packs sent, is shown in Figure 79.

Figure 79. Intervention group usage - Data packs per Week

Figure 80 shows the number of users who were used to using a smartphone before the study and the number of the users who had no experience of smartphones, for T1DM, T2DM, control group and intervention group.

Figure 80. Smartphone ownership

The results show that most of the patients (72,54%) already had experience with smartphone usage. 27,45% of patients had no experience in smartphone usage.

The usage of the PMDs for T1DM and T2DM were measured. Figure 81 shows the number of sessions per week and the number of data packs per week for each treatment dimension for T1DM. Each portion indicates the percentage for every treatment dimension.

Figure 81. Smartphone usage T1DM - Sessions per week

Figure 82 shows the number of sessions per week and the number of data packs per week for each treatment dimension for T1DM. Each portion indicates the percentage for every treatment dimension.

Figure 82. Smartphone usage T1DM - Data packs (Mb) sent per week

Figure 83 shows the number of sessions per week and the number of data packs per week for each treatment dimension for T2DM. Each portion indicates the percentage for every treatment dimension.

Figure 83. Smartphone usage T2DM - Sessions per week

Figure 84 shows the number of sessions per week and the number of data packs per week for each treatment dimension for T2DM. Each portion indicates the percentage for every treatment dimension.

Figure 84. Smartphone usage T2DM - Data packs (Mb) per week

6.2.2 Professional ICT experience

A log-file analysis was carried out to determine which modules of the Medical Panel were most used by the professionals during the project.

Five weeks of log-file data were collected, starting from the date of the patient data screening, carried out one week before the beginning of the treatment (Week 0). The results, shown in Figure 85, indicate that the most used sections were “Prescriptions” (31,76%) and “Clinical data,” (30,02%).

Figure 85. Medical Panel – Average numbers of interactions per module

The percentage of use for the other sections were: “Patient data and tools” (12,75%), “Patient lifestyle (13,80%) and “Educational messages” (11,67%). Statistical analysis of the MP usage is depicted in Table 6.4.

Table 6.4. MP interactions - Statistical analysis

Mean	207,984
Standard Error	23,38135
Standard Deviation	52,28228
Minimum	155,69
Maximum	288,82
Sum	1039,92

The mean, maximum and minimum usage times per patient were calculated for each week of the trial. Results are shown in Figure 86.

Figure 86. Mean usage time per patient

6.2.3 Professional MP Feedback – Organisational Task Adequacy survey

Medical professionals were asked to complete a custom-made survey, in order to find out if they thought the METABO system would fit well into the care routines and processes at their hospitals. This questionnaire allowed us to understand if, and how much, the EBF tools had contributed to the general usefulness of the clinician platform. The outcomes from clinicians showed that the system appeared to have a satisfactory or good fit into the existing routines (Figure 87). However, there were four items that were scored below the middle of the scale, which indicate considerable concerns by the users. These were items 9, 11, 14 and 15 of the survey. Medical doctors are thus particularly worried that METABO would...:

1. ...require many changes in existing work processes.
2. ...not allow medical doctors to spend more time with their patients.
3. ... not reflect currently existing administration processes well.
4. ... force them to work even on their days off.

Figure 87. Organisational Task Adequacy

6.2.4 Topics Knowledge results

In the area of patient education, the analysis was focused on assessing whether the intervention group gained more knowledge during the experimentation phase than the control group. Educational topics, shown in Table 6.5, were focused on diabetes main knowledge and self-management.

Table 6.5. List of topics

1	Knowledge about diabetes in general (basics, treatments, lifestyle)
2	Knowledge about hypoglycaemia and hyperglycaemia (causes, symptoms, consequences)
3	Knowledge about complications and co-morbidities
4	Knowledge about glycaemia monitoring and insulin
5	Knowledge about diabetic diet
6	Knowledge about physical activity for diabetic patients
7	Knowledge about pregnancy management for diabetic patients
8	Knowledge about diabetes management while travelling

Two quizzes of twenty-two questions were submitted at the beginning and at the end of the trial.

The graph in Figure 88 shows the knowledge gained from the first quiz, executed during the first baseline, to the second quiz, executed at the end of the trial. The gain of knowledge is expressed as a positive or negative percentage. The numbers in the graph refer to the list of topic, mentioned before. A knowledge gains of 5% could mean, for example, that the mean result in this category was 85%.

Figure 88. Knowledge Gain - Intervention and Control

Another study related to educational learning was based on asking both the patient control and intervention groups to answer questions about how they perceived the importance of the above mentioned topics. Results for intervention group are shown in Figure 89 and results from control group are shown in Figure 90.

Figure 89. Perceived importance of intervention group from B1 to B2

Figure 90. Perceived importance of control group from B1 to B2

6.2.5 Appraisal of Diabetes scale

In order to validate the estimation of quality of life, data from the Appraisal of Diabetes Scale (ADS) questionnaire were analysed. Figure 91 shows the results of ADS in B1 and B2 for control and intervention groups.

Figure 91. ADS – Intervention and Control groups

Figure 92 shows the results of ADS gathered from intervention and control groups in B1 and B2 and referred to each question of the survey.

Figure 92. ADS - B1 and B2 results for topic

6.2.6 Adoption of Good Practices – Motivation

The assessment of good practices in diabetes self-management were made through the Adoption of Good Practices survey. Figure 93 shows the results of the survey for intervention and control groups, respectively during B1 (Figure 93) and B2 (Figure 94).

Figure 93. Adoption of Good Practices - Motivation - B1

Figure 94. Adoption of Good Practices: Motivation - B2

The motivation of patients with regard to the Adoption of Good Practices (AGP) in diabetes treatment was measured in terms of medical prescription, weight control, physical exercise, diet and glycaemic control.

Figure 95 shows the general overview of the AGP outcomes from intervention and control groups in B1 and B2.

Figure 95. Adoption of Good Practices: Motivation

The comparison between intervention and control groups for each type of treatment at the end of the study is shown in Figure 96.

Figure 96. Adoption of Good Practices: Actual - B2

The Disease Control survey consisted on asking the patients about their current health condition and their treatment adherence during the last week. Results for intervention and control groups are shown in Figure 97.

Figure 97. Disease Control - B2

6.2.7 System Attractiveness

The user satisfaction was measured using the AttrakDiff questionnaire. The efficacy and the efficiency of both T1DM and T2DM applications were analysed and so the level of easy-to-use-interface. The user experience results for T1DM application are depicted in Figure 98.

Figure 98. User Experience - T1DM

The user experience results for T2DM application are depicted in Figure 99.

Figure 99. User Experience - T2DM

In the case of T1DM, the confidence interval of the pragmatic quality measure touches the middle of the scale, even though the mean value is situated above the critical mark of 3. Thus, our quality criterion is missed, even though by the least extent possible. As the other values are far above the middle, one may assume that the users saw the application very positively. One hypothetical explanation could be that the T1DM participants were very used to smartphones and might have considered the windows mobile platform as inferior to iOS or Android based systems.

6.2.8 Perceived Usefulness

Results from the Perceived Usefulness questionnaire were collected to assess the usefulness of the overall system within the diabetes treatment.

Figure 100. Perceived Usefulness differences between Intervention and control groups

Results show a general improvement of the estimation of the patient quality of life ($M=+4,40\%$; $SD= 1,1$). Intervention group improvement was $M=+4,60\%$; $SD= 0,9$, while control group improvement was $M=+3,60\%$; $SD= 0,8$.

Figure 101 shows the usefulness of the overall system for clinical professionals.

Figure 101. Perceived usefulness – Professionals

6.3 Results from collected AFMs

During and after the experimentation phase, collection and analysis of the AFMs were executed. Results were also collected from the log-files generated in the PMD, the server and the CP and the entries of the data base. The messages sent to and

from the EBF system and the log-files of the system and communication services were recorded over 4 weeks of the study.

A total of 2795 AFMs were submitted, representing an average of 107,50 messages per patient. The following table shows the messages collected during Phase 1 and Phase 2.

Table 6.6. Number of AFMs collected during the pilot

AFM Type	Phase 1	Phase 2	Total Number
Warnings	1443	811	2254
Reminders	143	107	250
Tips	109	92	201
Goals	42	42	90
Total	1732	1042	2795

The distribution of AFMs between T1DM and T2DM are shown in Table 6.7.

Table 6.7. AFM in T1DM and T2DM

AFM Type	T1DM	T2DM
Warnings	1133	1121
Reminders	132	118
Tips	98	103
Goals	0	90
Total	1367	1432

Apart from the AFM-Goals that were only assigned to the T2DM, no relevant differences are noted between the two groups.

6.3.1 AFM-Warnings

The average number of Warnings per patient was $86,69 \pm 45,06$, while the average of daily Warning per patient was $2,75 \pm 1,43$. The maximum number of Warning per day was 11. Further statistical results of the Warnings AFMs are illustrated in Table 6.8.

Table 6.8. Warnings - Descriptive Statistics

Warnings	
Average	86,69
Standard Error	8,84
Median	69,00

Mode	51,00
Standard Deviation	45,06
Sample Variance	2030,38
Range	167,00
Minimum	25,00
Maximum	192,00
Sum	2254,00
Count	26,00

Figure 102 shows the trend of the average number of Warnings sent to patients during the pilot. The graph indicates a considerable and linear decrease of messages during the treatment.

Figure 102. Average number of Warnings per day

The reduction in number of the Warnings messages between Phase 1 and Phase 2 can be appreciated looking at Figure 103. The average number of messages per day in the first part of the experiment was $3,26 \pm 0,44$ and it was $2,15 \pm 0,53$ in the second part.

Figure 103. Average of Warnings in Phase 1 and Phase 2

The average of Warnings per type of diabetes patient is shown in Table 6.9.

Table 6.9. Average Warnings T1DM-T2DM

	T1DM	T2DM
Average total Warning per patient	80,93±43,27	93,42±48,06
Average daily Warning per patient	2,59±1,42	2,94±1,49

The total number of Warnings, associated to the care plan's dimensions, as the corresponding mean and standard deviation information are shown in Table 6.10.

Table 6.10. Warnings associated to the care plan's dimensions

Dimension	Numbers	M	SD
Nutrition	659	25,35	10,80
Measurement	332	12,77	6,04
Medication	452	17,38	12,28

6.3.2 AFM-Reminders

The average number of Reminders per patient was 9,62±3,76, while the average number of daily Reminders per patient was 0,32±0,12. The maximum number of Reminders per day was 4. Further statistical results of the Reminders AFM are illustrated in Table 6.11.

Table 6.11. Reminders - Descriptive Statistics

Reminders	
Mean	9,62
Standard Error	0,74
Median	10,00
Mode	11,00
Standard Deviation	3,76
Sample Variance	14,17
Range	12,00
Minimum	3,00
Maximum	15,00
Sum	250,00
Count	26,00

Figure 104 shows the trend of the average number of Reminders sent to patients during the pilot. The graph indicates an increase trend of the messages number during the trial.

Figure 104. Average number of Reminders per day

The small increase number of Reminders between Phase 1 and Phase 2 can be observed in Figure 105. The mean of messages per day during the Phase 1 was $0,32 \pm 0,12$ and it is $0,33 \pm 0,56$ during the Phase 2.

Figure 105. Average of Reminders in Phase 1 and Phase 2

The mean of Reminders per type of diabetes patient is shown in Table 6.12.

Table 6.12. Average Reminders T1DM-T2DM

	T1DM	T2DM
Average total Reminders per patient	9,43±3,80	9,83±3,88
Average daily Reminders per patient	0,31±0,12	0,33±0,13

The total number of Reminders, associated to the care plan's dimensions, as the corresponding mean and standard deviation information are shown in Table 6.13.

Table 6.13. Reminders associated to the care plan's dimensions

Dimension	Numbers	M	SD
Nutrition	56	2,15	1,16
Measurement	30	2,00	0,65
Medication	51	1,96	1,00
Physical Activity	75	2,50	1,50
Education	38	1,81	0,75

6.3.3 AFM-Tips

The average number of Tips per patient was 7,91±4,08, while the average of daily Tips per patient was 0,26±0,13. The maximum number of Tips per day was 3. Further statistical results of the Tips AFMs are illustrated in Table 6.14.

Table 6.14. Tips - Descriptive Statistics

Tips	
Mean	7,91
Standard Error	0,85
Median	8,00
Mode	10,00
Standard Deviation	4,08
Sample Variance	16,63
Range	19,00
Minimum	1,00
Maximum	20,00
Sum	182,00
Count	23,00

Figure 106 shows the trend of the average number of Tips sent to patients during the pilot. As for the Reminders, the graph indicates a small increase of messages number.

Figure 106. Average number of Tips per day

The increase in the number of Tips between Phase 1 and Phase 2 can be observed in Figure 105. The average of messages per day during the Phase 1 was $0,32 \pm 0,12$ and it is $0,33 \pm 0,56$ during the Phase 2.

Figure 107. Average of Tips in Phase 1 and Phase 2

The average of Tips per type of diabetes patient is shown in Table 6.15.

Table 6.15. Average Tips T1DM-T2DM

	T1DM	T2DM
Average total Tips per patient	9,43±3,88	9,83±2,30
Average daily Tips per patient	0,31±1,61	0,33±0,08

The total number of Tips, associated to the care plan's dimensions, as the corresponding mean and standard deviation information are shown in Table 6.16.

Table 6.16. Tips associated to the care plan's dimensions

Dimension	Numbers	M	SD
Nutrition	49	1,88	1,07
Measurement	43	1,65	1,26
Medication	47	1,81	1,27
Physical Activity	24	1,14	0,91
Education	38	1,58	1,14

6.3.4 AFM-Goals

Twelve T2DM patients were involved in achieving Educational Goals and/or Weight Goal. The average number of Goals messages per patient was $7,50 \pm 2,71$, while the average of daily Goal per patient was $0,21 \pm 0,15$. The maximum number of Goals per day was 2. Further statistical results of the Goals AFMs are illustrated in Table 6.17.

Table 6.17. Goals - Descriptive Statistics

Goals	
Mean	7,50
Standard Error	0,78
Median	7,00
Mode	7,00
Standard Deviation	2,71
Sample Variance	7,36
Range	9,00
Minimum	5,00
Maximum	14,00
Sum	90,00
Count	12,00

Figure 108 shows the trend of the average number of Goals sent to patients during the pilot. The graph indicates a constant trend for number of messages sent during the trial.

Figure 108. Average number of Goals per day

The average of messages per day during the Phase 1 was $0,20 \pm 0,19$ and it is $0,22 \pm 0,12$ during the Phase 2.

Figure 109. Average of Goals in Phase 1 and Phase 2

The total number of Reminders, associated to the care plan's dimensions, as the corresponding mean and standard deviation information are shown in Table 6.18.

Table 6.18. Goals associated to the Care Plan's dimensions

Dimension	Numbers	M	SD
Physical Activity	22	1,83	1,80
Education	68	5,67	1,72

6.4 Results from ECHO

An ECHO-variable was calculated to measure how well the patients responded to the AFMs. Each time the patients did in the application what was required to be done, they received 10 points. Each time they looked up the respective educational content related to the AFM, they got 5 points. Skipping the message resulted in 2 points, as that is still better than ignoring the message completely by closing the application. We calculated the mean ECHO-score for each patient to see how much attention they paid to the AFMs.

The mean of the ECHO-score between Phase 1 and Phase 2 is shown in Figure 110.

Figure 110. ECHO-Score

The mean of the ECHO-score for T1DM between Phase 1 and Phase 2 is shown in Figure 111.

Figure 111. ECHO-Score T1DM

The mean of the ECHO-score for T2DM between Phase 1 and Phase 2 is shown in Figure 112.

Figure 112. ECHO-Score T2DM

No ECHO was calculated for the Tips, since for this AFM, no other options were allowed apart from confirming the reading.

6.5 Treatment Adherence and Usage Adherence results

The indices of adherence in treatment and in usage were measured during the five weeks and analysed between Phase 1 and Phase 2. Due to poor data inputs, the adherence for the Measurement dimensions have been limited to the blood glucose self-checks.

6.5.1 Intervention Group – Adherence indices

Figure 113 shows the levels of the Treatment Adherence indicators for the intervention group between the first half (Phase 1) and the second half (Phase 2) of the trial.

As shown from the graph, favourable outcomes are observed for adherence: nutrition ($M=+13,92\%$; $SD=18,14$), blood glucose entry measurements ($M=+5,50\%$; $SD=26,87$), medication ($M=+5,83\%$; $SD=8,07\%$), physical activity ($M=+5,32\%$; $SD=12,65$) and education ($M=+12,89\%$; $SD=23,05$).

Figure 113. Treatment Adherence during Phase 1 and Phase 2 for Intervention group

Figure 114 shows the levels of the Usage Adherence indicators for the intervention group between the first half (Phase 1) and the second half (Phase 2) of the trial.

Also in this case, results denote a general improvement on each prescription sub-group: nutrition ($M=+4,39\%$; $SD=14,87$), blood glucose entry measurements ($M=+2,97\%$; $SD=9,55$), medication ($M=+5,83\%$; $SD=8,07\%$), physical activity ($M=+2,92\%$; $SD=13,65$) and education ($M=+10,00\%$; $SD=16,15$).

Figure 114. Usage Adherence during Phase 1 and Phase 2 for intervention group

A complete analysis, summarised in Table 6.19, compares the difference (Δ) between Phase 1 and Phase 2 of the adherence of treatment and usage, in terms of mean (M), standard deviation (SD), minimum (Min), maximum (Max) and 95 per cent confidence interval (CI).

Table 6.19. Treatment and Usage adherence indices during the trial

	M	SD	Min	Max	CI
ΔNU_TA	13,92	18,14	23	92	4,55
ΔNU_UA	4,39	14,87	41	79	6,09
ΔME_TA	5,5	26,87	35	88	4,11
ΔME_UA	2,97	9,55	-20	77	5,24
ΔMD_TA	5,83	8,07	23	93	6,53
ΔMD_UA	5,83	8,07	23	93	6,53
ΔPA_TA	5,32	12,65	-12	50	5,39
ΔPA_UA	2,92	13,65	-6	55	3,71
ΔED_TA	12,89	23,05	25	11	2,10
ΔED_UA	10	16,15	22	22	1,80

Even if some improvements, especially on treatment adherence, can be considered small, these results have been reached during only a five-week period, revealing a high potential on the implemented methods.

6.5.2 Control Group – Adherence indices

The control group did not use the mobile application, so the adherence indices were derived from the analysis of the patient's diaries. The users were asked to report only information on nutrition, glycaemic measurements and medication intakes. Therefore, it was not possible to collect data from physical activity and educational content prescriptions. Moreover, information of treatment adherence levels for nutrition and measurement from diaries were not consistent for a qualitative analysis, so the adherence results have been limited to the adherence in usage. The results are shown in Figure 115. The graph indicates a low decrease in Nutrition ($M=-1,60\%$; $SD=1,01$), an increase in Measurement ($M=3,67\%$; $SD=2,05$) and an increase in Medication adherence ($M=+2,90\%$; $SD=1,18\%$).

Figure 115. Usage Adherence during Phase 1 and Phase 2 for control group

Comparing the results from control and intervention groups reveals a significant inclination of the intervention group on being more compliant in the usage of the system, as shown in Table 6.20.

Table 6.20. Usage Adherence difference between control group and intervention group

		Phase 1			Phase 2		
		Intervention	Control	Difference	Intervention	Control	Difference
Nutrition	M	76,23	78,54	-2,31	80,62	76,94	3,68
	SD	9,29	8,62	0,67	9,61	7,96	1,65
	Min	57,00	50,00	7,00	59,00	53,00	6,00
	Max	93,00	95,00	-2,00	98,00	97,00	1,00
	CI	3,57	3,76	-0,19	3,69	4,68	-0,99

Measurement	M	81,15	83,01	-1,86	84,12	86,68	-2,56
	SD	16,01	13,70	2,31	17,34	15,65	1,69
	Min	21,00	25,90	-4,90	29,00	32,00	-3,00
	Max	100,00	99,00	1,00	100,00	93,00	7,00
	CI	6,15	4,50	1,65	6,66	7,49	-0,83
Medication	M	85,40	88,15	-2,75	91,23	91,05	0,18
	SD	15,55	12,82	2,73	8,68	6,58	2,10
	Min	20,00	31,00	-11,00	57,00	55,00	2,00
	Max	100,00	100,00	0,00	100,00	100,00	0,00
	CI	5,98	6,80	-0,82	3,34	2,90	0,44

6.5.3 Differences between T1DM and T2DM

In this study, the treatment and usage adherence levels have also been oriented to evaluate any difference between T1DM and T2DM of the intervention group.

The levels of the Treatment Adherence indicators for T1DM between the first half (Phase 1) and the second half (Phase 2) of the trial are shown in Figure 116.

Figure 116. Treatment Adherence during Phase 1 and Phase 2 for T1DM

The levels of the User Adherence indicators for T1DM between the first half (Phase 1) and the second half (Phase 2) of the trial are shown in Figure 117.

Figure 117. Usage Adherence during Phase 1 and Phase 2 for T1DM

The levels of the Treatment Adherence indicators for T2DM between the first half (Phase 1) and the second half (Phase 2) of the trial are shown in Figure 118.

Figure 118. Treatment Adherence during Phase 1 and Phase 2 for T2DM

The levels of the Usage Adherence indicators for T2DM between the first half (Phase 1) and the second half (Phase 2) of the trial are shown in Figure 119.

Figure 119. Usage Adherence during Phase 1 and Phase 2 for T2DM

Concerning the treatment adherence, as shown from the previous graphs, T1DM patients reported more adherence than T2DM in glycaemic level control and medication intake, while T2DM reported more adherence than T1DM in nutrition, physical activity and education.

With respect to the usage adherence, T1DM reported more usage than T2DM in diet control, medicine intake and physical activity, while T2DM reported more usage than T1DM in glucose and education.

6.6 EBF Perceived Usefulness

The results presented here are focused on acceptance and effectiveness of the EBF. The survey results of the patients' satisfaction are shown in Figure 120. In the case of patients, attractiveness is 3,8 on average ($SD = 1,1$), which indicates a good appreciation. Answers related to kindness ($M = 3,5$; $SD = 1,15$), indicate that patients did not consider the messages to be annoying or harassing. Even if only 33% of the patients considered they would have not reached the assigned goals without the feedback assistant system (Persuasiveness, $M = 2,8$; $SD = 1,35$), more than 85% acknowledged the helpfulness of the method ($M = 3,6$; $SD = 1,91$). Furthermore, 93% of patients considered the messages reflected their true health status, confirming the accuracy of the system ($M = 4,3$; $SD = 0,74$) in terms of time precision in delivering messages. Message truthfulness was considered positively ($M = 3,5$; $SD = 0,91$), system timeliness on dispatching message was even better ($M = 3,9$; $SD = 1,09$) and perceived adherence of patients (i.e., "METABO messages did not help me follow my medical prescription better than before") was also high ($M = 3,7$; $SD = 1,10$).

Figure 120. Patient EBF survey results

The analysis of the differences between T1DM and T2DM is shown in Figure 121.

Patients - EBF Evaluation Survey

Figure 121. EBF Survey T1DM-T2DM

Acceptance was also measured with caregivers. Results are shown in Figure 122.

Figure 122. Professionals EBF survey results

Professionals found the EBF functionalities highly useful ($M = 3,9$; $SD = 0,94$), in relation to monitoring patient's adherence and to adjusting remote feedback. Nonetheless, 35% considered the system should inform them more actively about a problematic status or behaviour of a patient (system resoluteness with $M = 3,3$; $SD = 1,12$). Accuracy ($M = 3,7$; $SD = 1,08$), completeness ($M = 3,4$; $SD = 0,90$) and usefulness ($M = 3,9$; $SD = 0,94$) were found to be high, indicating that dispatched information was correct, plausible and sent in a way that did not annoy professionals unnecessarily.

6.7 Results of the Goal-Setting intervention

During the first medical visit, the T2DM patients of the intervention group were asked to be involved in the goal-setting intervention. Compliance with the given goals was measured through logging of all activities of the study. All T2DM agreed on performing one or more Goal-setting objectives. Six "Lose Weight" and ten "Improve Educational Content" goals were set. The educational goals consisted of asking the patients to improve their final level of education from a starting level. The starting level was given from the Topics Knowledge questionnaire results. A patient whose initial level is Beginner can be asked to achieve an Intermediate or Advanced final level.

Even if the weight goal was also set as an additional challenge for motivating the patients, the limited period of time of the trial was clearly not enough to achieve

such a long term objective. The overview of the achieved goal with respect to the assigned ones is represented in Figure 123.

Figure 123. Goals T2DM

6.8 Discussion of the results

A discussion of the results and how they contribute to the research questions is included in this sub-section. The analyses and discussions of the results refer to the impact of the framework intervention in the patient's care plan and professional's follow up.

6.8.1 Patient ICT experience

The analysis of the log-files related to the patient ICT experience revealed an average use of the PMD of 6,55 hours per week. The result corresponds to an average of more than 56 minutes of usage per day, therefore highly significant from the usage adherence point of view.

The results show a disparity of the T1DM and T2DM differences between hours per week usage and data pack sent: even if the amount of the data packs sent between T1DM and T2DM is pretty similar, the T2DM system usage was 11,98% more than T1DM concerning the hours per week. This can be due to the fact that the T2DM patients need more time to enter the inputs or because they spent more time using the PMD without sending data, for instance reading topics on the educational content module or looking at the graphic tools.

The greater value of usage per hours of T2DM is not correlated with the results of the T2DM usage adherence, since it was lower than the T1DM. This could be due to the fact that, even if T2DM were more active in the use of the PMD in terms of hours per week, they were less effective in terms of adhering to system usage.

The analysis of the data packs sent per week of T1DM and T2DM showed that most of the data source sent was derived from the modules for medication, measurements and food. As foreseen, the inputs for the physical activities required less effort. The number of sessions per week increases in both T1DM (+10,49%) and T2DM (+4,33%), and the data packs sent per week increased by 10,90% in T1DM and 3,86% in T2DM.

6.8.2 Professional ICT experience

The analysis of the log-files related to the professional ICT experience indicates that the professionals have used with high frequency the tools where the EBF functionalities were integrated: the “Patient data & tool”, that includes the AFM tool for checking the feedback messages sent to patients and the “Clinical Data”, which includes the Care Plane Adherence tool. The most usage for The AFM tool was observed in Week 2, while the most usage of the AFM Care Plan Adherence tool was observed in Week 3 (Table 6.21). The results are expressed in terms of number of weekly interactions per patient.

Table 6.21. MP_AFM tool interaction - Professional

MP - AFM Tool interaction				
	Week 1	Week 2	Week 3	Week 4
Average	0,81	1,15	1,00	0,35
Standard Deviation	0,69	1,08	1,06	0,56
Min	0	0	1	0
Max	2	4	3	2
Confidence Interval	0,27	0,42	0,41	0,22
Sum	21	30	26	19

The information about the frequency usage of the Care Plan Adherence tool is shown in Table 6.22. The results are expressed in terms of number of weekly interactions per patient.

Table 6.22. MP_AFM tool interaction - Professional

MP - Care Plan Adherence				
	Week 1	Week 2	Week 3	Week 4
Average	0,96	0,58	0,96	0,69
Standard Deviation	0,82	0,64	0,60	0,68
Min	0	0	0	1
Max	3	2	2	2
Confidence Interval	0,32	0,25	0,23	0,26
Sum	24	15	26	23

From the outcomes of the Organisational Task Adequacy survey, it is not clear what the EBF functionalities have contributed to the clinicians' feedbacks on the overall system. According to these results, it is evident that clinicians do not consider the system will allow them to optimise the time spent with their patients during the visits. Even though, the analysis from the EBF survey indicated that the professionals found the EBF functionalities very useful in terms of patient behaviour follow-up. These feedback divergences allow us to suppose that the outcomes from the Organisational Task Adequacy do not refer to EBF. At the same time, the results indicate that the EBF did not contribute to determine a positive usefulness of the overall METABO system.

6.8.3 Analysis of the AFMs and ECHO

Results from the gathered AFMs show a decrease of high priority messages over time, indicating lesser Warnings from Phase 1 ($M = 3,26$; $SD = 0,44$) to Phase 2 ($M = 2,15$; $SD = 0,53$). Regarding the Reminders, the Tips and the Goals, very small increase of messages is observed, as shown from the figures in 6.3. On the whole, the results from the number of Warnings are in accordance with the overall improvement of adherence shown in 6.4, while the number of Reminders is not: a decrease in number was also expected in Phase 2. This can be explained by the fact that, for those patients who had low levels of adherence, lots of AFMs were sent, resulting on an overall increase in average or the Reminders. Most of the Warnings came from Nutrition, mainly because the users forgot to insert the meals' inputs or because they didn't want to, being this dimension's inputs very demanding. The highest number of Reminders were from the Physical Activity.

As expected, T1DM patients were more loaded with ST advices through Warnings, in accordance with their condition. Similarly, being the focus of T2DM on LT sustainable lifestyle changes, T2DM received more Reminders, as for physical activity.

The outcomes from the ECHO-scores show a decrease of the scores from Phase 1 to Phase 2 for both Warnings (from 23,31 to 20,89) and Reminders (from 8,26 to 7,69), while an increase in Goals (from 5,75 to 7,33). The decrease in the score is probably caused by the fact that, after receiving lots of AMFs, patients were tired and started to skip them.

Differences in ECHO-score between T1DM and T2DM were found in the Warnings, since T1DM had a higher level (from 26,32 to 24,82) than T2DM (from 20,30 to 16,96) and in the Reminders, where T2DM showed a better feedback (from 7,02 to 7,55) than the T1DM (from 9,12 to 6,92).

6.8.4 Goal-Setting intervention and diabetes management indicators correlation

Considering the information from the knowledge gained, estimated through the educational quizzes performed at the beginning and at the end of the trial, the outcomes, shown in Table 6.23, indicate the intervention group improved the mean of correct answers ($M = +5,07\%$; $SD = 0,12$), improving its level of knowledge (Δ Education), while the control group denotes a low decrease ($M = -1,09\%$; $SD = 0,12$).

Table 6.23. Analysis results from educational level quizzes

		Control Group	Intervention Group
Δ Education	M	-1,09%	5,07%
	SD	0,12	0,12
T-Test		7,28%	

T-test analysis reveals no significant differences between the groups ($p > 0,05$).

The improvement of level of knowledge has been compared with the results obtained with the assigned educational goals. As shown in Figure 124, eight patients achieved an improvement in their educational knowledge within their care plan with the goal-setting intervention. A correlation between this data and the patient knowledge gain was identified: patients that were involved in educational goals had more knowledge gain than the rest of the intervention group. Figure 124 shows the differences between the two groups.

Figure 124. Knowledge gain – Education Goal-Setting

As shown, the average of knowledge gain achieved by patients involved in goal-setting intervention was $M=+4,73$; $SD=1,72$ while the average of knowledge gain achieved by patients not involved in goal-setting intervention was almost null ($M=+0,07$; $SD=0,02$).

Finally, the outcomes from the Perceived Important survey, employed to assess the patient perceived importance about the topics mentioned in the quizzes, indicate a low increase levels of the intervention group ($M=+4\%$; $SD=1,65\%$) and of the control group ($M=+1,75\%$; $SD=0,8\%$), not statistically significant.

The ADS survey was used within the EBF strategy to assign to patients the stage of change level at the beginning of the care plan. The survey was completed by both intervention and control groups at the end of the trial, in order to analyse possible differences between the two baseline periods. The results show a general improvement of the estimation of the patient quality of life ($M=+4,40\%$; $SD= 0,3$). Intervention group improvement was $M=+4,60\%$; $SD= 0,3$, while control group improvement was $M=+3,60\%$; $SD= 0,09$.

These results show that it is not possible to prove any beneficial effect of the general system on the quality of life of the participating patients and even less the relative contribution of the EBF intervention. Due to the small effect size to be expected, inferential statistics were not performed.

The analysis of the AGP survey results shows an improvement of the intervention group to assess the degree of implementation of the good practices from B1 to B2

($M=+8,0\%$; $SD=2,21$) and a small decrease in the control group ($M=-3,87\%$; $SD=0,33$). An investigation to determine possible correlations between the improvement of good practices in the intervention group and the EBF intervention on the patient side was conducted. An analysis aimed at identifying the correlations between AGP results and patients assigned to a goal intervention found no significant statistical correlation between the AGP and the goal intervention (Table 6.24).

Table 6.24. Pearson correlation between Goal-Setting intervention and AFMs, ADS, AGP

Goal-Setting Intervention	
Change in ADS (High score = self-management improved)	$r = ,078$ $p = ,807$ $N = 12$
Δ AGP-Motivation (High score = motivation improvement)	$r = ,055$ $p = ,059$ $N = 12$
AGP-Actual (High score = better patient state)	$r = ,030$ $p = ,925$ $N = 12$

6.8.5 Correlation between the EBF effects and the diabetes management indicators

It is difficult to say, which effect the AFMs themselves had on the patients, independent of the rest of the system. We would need a separate controlled experiment in which we could have manipulated the AFMs to find that out. Nevertheless, we can analyse the existing data and try to find data that at least indicates that the messages were possibly not helpful.

The worse a patient's treatment and usage adherence were, the more Warnings and Reminders were sent to the corresponding care plan's dimensions. This means that if a patient received a lot of messages, they were performing poorly at a certain stage. The AFMs should have helped to level out the difference in adherence between patients: patients with (initially) poorer performance should have achieved the same outcomes than better performing patients at the end of the pilot. Hence, the Pearson correlation between the number of AFMs sent and the adherence outcome should be close to 0 and its significance value p should be greater than, 20 (best: 1,0). Results of the ADS and treatment adherence correlation are shown in Table 6.25.

As indicated, the total number of Warnings sent correlates very low and insignificantly with the change in the ADS and with the Treatment Adherence. Even though,

there is a significant positive relationship between the number of Warnings and the levels of Usage Adherence. That means: when a higher number of Warnings were sent, the patients improved in Usage Adherence, more than the other patients. This indicates that the AFMs were probably useful.

Regarding the Reminders, the number of messages correlates non-significantly yet even positively with the changes in ADS and with the adherence indicators. This can be interpreted positively in terms of AFMs usefulness: when a higher number of Reminders were sent, the patients improved even more than the other patients.

Table 6.25. Pearson correlation AFMs, ADS, adherence's indices.

	Number of Warnings	Number of Reminders
Change in ADS (High score = patient improved)	$r = -,083$ $p = ,713$ $N = 22$	$r = ,479$ $p = ,208$ $N = 22$
Treatment Adherence (High score = patient adheres better)	$r = -,038$ $p = ,855$ $N = 26$	$r = ,399$ $p = ,229$ $N = 26$
Usage Adherence (High score = patient adheres better)	$r = ,679$ $p = ,023$ $N = 26$	$r = ,406$ $p = ,241$ $N = 26$

Regarding the ECHO-variable, calculated to measure the patient's feedback when receiving an AFM, we also correlated the ECHO-score to the outcome-variables. If the correlation was significantly negative, the patients would not have profited from giving a good response to the AFMs, thus indicating the usefulness of the messages.

Table 6.26. Pearson correlation ECHO and ADS, AGP, Disease Control, Adherence's indices.

	ECHO of Warnings	ECHO of Reminders
Change in ADS (High score = self-management improved)	$r = -,273$ $p = ,219$ $N = 22$	$r = -,097$ $p = ,667$ $N = 22$
Δ AGP-Motivation (High score = motivation improvement)	$r = ,247$ $p = ,269$ $N = 22$	$r = ,509$ $p = ,016$ $N = 22$
AGP-Actual (High score = better patient state)	$r = ,147$ $p = ,515$ $N = 22$	$r = ,360$ $p = ,100$ $N = 22$

Disease Control (High score = better patient state)	$r = -.242$ $p = .277$ $N = 22$	$r = .082$ $p = .717$ $N = 22$
Treatment Adherence (High score = patient adheres better)	$r = .041$ $p = .841$ $N = 26$	$r = -.014$ $p = .947$ $N = 26$
Usage Adherence (High score = patient adheres better)	$r = .022$ $p = .730$ $N = 26$	$r = -.016$ $p = .938$ $N = 26$

In this case, the results were calculated for all outcome variables as the interpretation is more complex. We see that actually, the ECHO-score of warnings correlates negatively with the change in Appraisal and with Disease Control, although not significantly in this small sample. However, the correlation is non-significantly positive for Adoption of Good Practices – Change in motivation and Adoption of good practices – Actual state. And the correlation is close to 0 for Treatment Adherence and Usage Adherence. This means that patients who paid more attention to the AFMs and showed a good ECHO rather felt that their diabetes was more difficult to control and that it had a rather negative impact on their lives. However, these patients gained positive motivation and improved their behaviour (according to their self-assessment) more than the other patients during the pilot. There are two possible explanations for this:

1. Patients who receive AFMs (and generally input from the outside) more seriously, have or develop a rather pessimistic impression of their disease, while they also accept the call to improvement contained in the message.
2. Patients who are generally feeling that they cannot control their disease alone pay more attention to the AFMs, and thus improve their motivation and behaviour along with the messages.

Other analysis was aimed at identifying possible correlations between AFMs and the viewpoint of patients with regard to the quantity of messages received as indicated in the EBF survey. The outcomes are shown Table 6.27.

Table 6.27. Pearson correlation between AFMs and EBF survey

	Number of Warnings	Number of Reminders
Many messages were too annoying	r = ,761 p = ,031 N = 25	r = 0,11 p = ,578 N = 25
The EBF sent me too many useless messages	r = ,092 p = ,661 N = 25	r = ,098 p = ,637 N = 25

According to the results, there is a significant positive relationship between the number of Warnings received and the fact some users considered many AFMs too annoying. This could be interpreted as: when patients received too many warning messages, they start to be tired of reading them.

Another correlation was conducted between the ECHO and EBF survey (Table 6.28).

Table 6.28. Pearson correlation between ECHO and EBF survey

	ECHO of Warnings	ECHO of Reminders
Many messages were too annoying	r = -,403 p = ,045 N = 25	r = ,184 p = ,378 N = 25
The EBF sent me too many useless messages	r = -,296 p = ,150 N = 25	r = ,179 p = ,390 N = 25

The ECHO of Warnings has a statistically significant negative correlation with the variable that measured to which extent the participants found the messages annoying. That means that people who responded very well to the Warning messages found them less annoying. The correlation of the ECHO of Warnings and the variable that measured the perceived uselessness of the AFMs shows the same tendency, although the correlation is weaker in this sample. This is not surprising: Some patients appreciated the messages more than others and found them more helpful, which lead to a better response (ECHO) behaviour in these cases.

Interestingly, this pattern is not repeated for the ECHO of reminders. The correlations are close to 0 but positive. One explanation of this effect may be that participants did not question the "usefulness" or the number of reminders. Reminders just focus the patients' attention to a task that they already know about. So, it is difficult to argue against the usefulness of a Reminder. Warnings however may be

wrong or useless and thus annoying when they warn about an event that was not really going to happen or a danger that the patients was already aware of.

Last analysis was focused on assessing a possible correlation between the perceived usefulness of the overall system and the EBF intervention. Results are shown in Table 6.29.

Table 6.29. Pearson Correlation between the overall system perceived usefulness and the EBF

	Perceived Usefulness
The messages sent to me by the EBF have helped me improve my health	$r = ,215$ $p = ,300$ $N = 25$
The messages sent to me by the EBF reflect my true health status	$r = ,221$ $p = ,287$ $N = 25$
The messages did help me follow my medical prescription better than before	$r = ,360$ $p = ,076$ $N = 25$

These outcomes indicate there is a significant positive relationship between the perceived usefulness of the overall system and the EBF intervention when dispatching the AFMs. This result can be also interpreted positively from an EBF usefulness point of view.

In summary, we cannot say with certainty whether the AFMs were helpful for the patients, based on the existing empirical data collected in the pilots. However, results have shown improvements in usage adherence for patients who received many Warnings, while non-significantly yet even positive indicators related to both treatment and usage correlated with the Reminders.

If the messages were useless, we would presumably have seen a different data pattern than what was shown above. Patients who received many AFMs (due to not complying with certain requirements of the EBF) did not worse, or even better in the end than the other patients. Patients who paid a lot of attention to the AFMs were not worse in treatment adherence and showed both, more concern about their disease but also more motivation to tackle the obstacles. This suggests that the effect of messages on a patient may depend on individual factors, including but not restricted to their current appraisal and level of control. However, the AFMs seemed to help those patients who did not take their treatment seriously enough in the beginning and who were willing to respond to the messages they received.

Finally, patients who received too many Warnings, started to consider the message dispatch to be a bit stressful.

6.8.6 Encountered Technical problems

During the trial preparation phase, crash and stability issues were identified in the Windows Mobile application. During the first five user's pilot, the version of the software application has been updated, without losing log-file information. A few connection issues were identified between both Windows Mobile and iOS applications and the Central Server, due to web service communication bugs, that have been successively solved without compromising the quality storage of pilot's data.

Chapter 7

Conclusions and Future Work

7.1 Conclusions

This chapter presents the conclusions of the research work accomplished, contrasting the hypothesis and objectives set up at the beginning of the work with the obtained results. The hypotheses of this research were the following:

Hypothesis 1: It is possible to define a set of criteria to measure adherence in diabetic patients.

This research work has proven this hypothesis and has defined a set of criteria that constitute the basis for defining the technological framework. The criteria are based on the definition of the treatment adherence and the usage adherence indices, calculated through five care plan dimensions: Nutrition (NU), Physical Activity (PA), Medication (ME), Measurements (MS) and Education (ED).

Hypothesis 2: It is possible to design a technological framework, based on the aforementioned criteria and behavioural change theories, to engage diabetic patients in managing their disease and adhere to care plans.

The framework has been designed through the selection of four methods consisting in behavioural change theories, guidelines from effective health communication and principles of persuasion applied to technology.

Hypothesis 3: It is possible to implement the technological framework in the mobile health domain.

Based on the aforementioned criteria and theories, the technological framework has been built using user-centered design and RUP methodologies.

Hypothesis 4: It is possible to use the technological framework as a mobile health solution in a real context and have positive effects in terms of diabetes management indicators.

The effectiveness of the technological framework has been proved in a clinical study where the different functionalities of the system were assessed.

The validation has been focused on assessing the effects that the utilisation of a framework with these characteristics has on the diabetic patients. The analysis of the validation has proven that the EBF supports diabetic patients in improving adherence to a care plan.

CONCLUSION

Final conclusion

Based on the results presented above and in the previous chapters, we can conclude that the research work presented achieved the main objective set up at the beginning: to **develop of a technological framework, based on behavioural change theories applied to a mHealth domain that allows the improvement of adherence treatment in diabetic patients.**

7.2 Original Contributions

This research work includes the following main original contributions:

Definition of the criteria for the measurement of the treatment adherence and the usage adherence

A set of criteria, based on mathematical equations and conditions, have been defined for estimating the adherence of a diabetic patient to the recommended care plan. These criteria foresee a set of indices to measure the patient's adherence to the treatment and to the system usage. Five dimensions of adherence are defined: Nutrition, Physical Activity, Medication, Measurements, composed of Glycaemic Level, Weight and Blood Pressure, and Education.

Design of a technological framework, based on the adherences' criteria and based on behavioural changes methods

More specifically, the following elements have been defined by the author of this research work:

- Definition of the AFM and definition of the rules for scheduling and dispatching the AFM
- Definition of the Engagement Behavioural Framework architecture basing on four change behavioural methods

Implementation of the technological framework

The following elements have been designed and developed:

- EBF for T1DM application for Windows Mobile OS
- EBF for T2DM application for iOS

Definition, implementation and evaluation of the Engagement Behavioural Framework survey

An online survey, composed on ten questions, has been defined, implemented in four languages through the LimeSurvey platform, validated by professionals and filled in by patients and caregivers during the pilot studies, for assessing the usefulness of the framework.

7.3 Future development

This research work constitutes an intention of demonstrating that a technological solution, based on behavioural change theories, applied to mHealth domain, allows improving adherence in diabetic patients.

The evaluation AFMs strategy implemented within the EBF and the expected outcomes must be further investigated. The examination of how and to what extent each behavioural change theory has affected on the outcomes of the research work, should be performed. Moreover, complementary methods for interpreting in real-time the patient's behaviour when reacting to messages should be integrated. An example could be the adoption of the Elaboration Likelihood Model, conceived for describing the change of attitudes when processing a message.

The proposed research work aimed at demonstrating the potential functionalities of a technological framework. Further research includes the possibility to integrate less invasive wearable and wireless technology for the metabolic and life activities measurements. Also assistive technology solutions for manual inputs of data will be integrated, for instance through direct voice devices.

The proposed architecture will be used as a starting point for the feedback generation mechanism in the ongoing European project NEVERMIND. The aim of the NEVERMIND project is the early detection, prevention and treatment of depression symptoms, as a co-morbidity in patients that suffer from a chronic disease such as myocardial infarction, leg-amputation, cancer, and kidney failure. For the scope of this project, the EBF will be improved by using a more complex patient model that will take into account:

- Dynamic Real-Time Mood: the mood will be tracked using multi-dimensional scales and questionnaires
- Social activity: the App will track a set of indicators for the patient's social life, like number of phone calls, messages, and any kind of social interaction that can be done with the use of a smartphone. A special focus will be given to the communication between the patient and their formal and informal caregivers.

Such new dimensions will be used to:

- Recognise, interpret and model the patient's emotional status, using theories derived from affective computing

- Adapt and personalise the feedback generation to the patient emotional status

Finally, the research work can be continued in the future addressing further research lines, such as adding functionalities for enhancing patient-to-patient support and integrate accessibility features.

References

References

- Aagaard-Hansen, J. & Chaignat, C.L., 2010. Equity, social determinants and public health programmes. *Equity, social determinants and public health programmes*, p.77ff.
- AARP Public Policy Institute, 2014. Chronic Conditions Among Older Americans. In *Beyond 50.09: Chronic Care: a Call to Action for Health Reform*. pp. 9–33. Available at: http://www.aarp.org/health/medicare-insurance/info-03-2009/beyond_50_hcr.html.
- Adams, S.Y. et al., 2009. The effects of a computer-tailored message on secondary prevention in type 2 diabetes: a randomized trial. *Population health management*, 12(4), pp.197–204. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3191380&tool=pmcentrez&rendertype=abstract>.
- Adejoh, S.O., 2014. Diabetes Knowledge, Health Belief, and Diabetes Management Among the Igala, Nigeria. *SAGE Open*, 4(2), p.2158244014539966–. Available at: <http://sgo.sagepub.com/content/4/2/2158244014539966>.
- Adler-Milstein, J. et al., 2007. *The value of information technology-enabled diabetes management*,
- Affairs., T.U.N.D. of E. and S., 2013. *World Population Ageing 2013*, Available at: [http://www.aaojournal.org/article/S0161-6420\(99\)00048-2/fulltext\npapers3://publication/doi/10.1016/S0161-6420\(99\)00048-2](http://www.aaojournal.org/article/S0161-6420(99)00048-2/fulltext\npapers3://publication/doi/10.1016/S0161-6420(99)00048-2).
- Agency for health care research and quality, 2014. Health IT for Improved Chronic Disease Management. Available at: <http://healthit.ahrq.gov/ahrq-funded-projects/emerging-lessons/health-it-improved-chronic-disease-management> [Accessed May 3, 2015].
- Aguiree F, Brown A, Cho NH, Dahlquist G, Dodd S, Dunning T, Hirst M, Hwang C, Magliano D, Patterson C, Scott C, Shaw J, Soltesz G, Usher-Smith J, W.D., 2013. *IDF Diabetes Atlas: sixth edition*,
- Allen, C. M. C., & Lueck, C.J., 1999. Diseases of the nervous system. *Davidson's Principles and Practice of Medicine*, 18th ed.(Churchill Livingstone, London).
- American Diabetes Association, 2008. Nutrition recommendations and interventions for diabetes: A position statement of the American Diabetes Association. *Diabetes Care*, 31(1), pp.61–78.
- Anderson, R.J. et al., 2001. The Prevalence of Comorbid Depression in Adults With Diabetes. *Diabetes Care*, 24(6), pp.1069–78.
- Andres, A., Gomez, J., & Saldana, C., 2008. Challenges and applications of the transtheoretical model in patients with diabetes mellitus. *Disease Management & Health Outcomes*, 16(1)(118), pp.31–46. Available at: <http://link.springer.com/article/10.2165/00115677-200816010-00004>.
- Apfel, F. & Tsouros, A.D., 2013. *Health literacy: The solid facts*,

- Ashish Atreja, MD, MPH, Fellow, Naresh Bellam, MD, MPH, Resident Physician, and Susan R. Levy, PhD, P.E., 2005. Strategies to Enhance Patient Adherence: Making it Simple. *MedGenMed*, 7(1): 4. Available at: <https://www.dovepress.com/adherence-and-health-care-costs-peer-reviewed-fulltext-article-RMHP#>.
- Association, A.T., 2006. Telemedicine, Telehealth, and Health Information Technology. *An ATA Issue Paper*, (May), pp.1–13.
- Avery, L. et al., 2012. Changing physical activity behavior in type 2 diabetes: A systematic review and meta-analysis of behavioral interventions. *Diabetes Care*, 35, pp.2681–2689.
- Avery, L. et al., 2015. Successful behavioural strategies to increase physical activity and improve glucose control in adults with Type 2 diabetes. *Diabetic Medicine*, p.n/a–n/a. Available at: <http://doi.wiley.com/10.1111/dme.12738>.
- Bassuk, Shari, S. & Manson, J.E., 2005. Epidemiological evidence for the role of physical activity in reducing risk of type 2 diabetes and cardiovascular disease. *J Appl Physiol*, 99(44), pp.1193–1204.
- Beaglehole, R., Epping-Jordan, J. & Patel, V., 2008. Improving the prevention and management of chronic disease in low-income and middle-income countries: a priority for primary health care. *Lancet*, 372, pp.940–949. Available at: http://ssu.ac.ir/fileadmin/templates/fa/daneshkadaha/daneshkade-behdasht/manager_group/upload_manager_group/manabe_elmi/maghalat_e_amuzeshi/english/4olympiad-sathbandi_gheir_vagi/improving_the_prevention_manage_ment.pdf.
- Blanchet, K., 2008. Telehealth and Diabetes Monitoring. *Telemedicine and e-Health*, pp.744–747.
- Bodenheimer McGregor, K., Sharifi, C., T., 2005. Helping patients manage their chronic conditions. , (June), p.25p. Available at: http://www.chcf.org/~media/MEDIA_LIBRARY/Files/PDF/H/PDF/HelpingPatientsManageTheirChronicConditions.pdf.
- BodyMedia, 2013. BodyMedia SenseWear System. Available at: <http://sensewear.bodymedia.com/SW-Learn-More/Product-Overview> [Accessed May 7, 2014].
- Bradley, C., 1994. Diabetes Treatment Satisfaction Questionnaire (DTSQ). *Handbook of Psychology and Diabetes*, pp.111–132.
- Care, M., 2008. Standards of Medical Care in Diabetes -2008. *Diabetes Care*, 31(Supplement 1), pp.S12–S54. Available at: <http://care.diabetesjournals.org/cgi/doi/10.2337/dc08-S012>.
- Care, S.O.F. & Practice, C., 1994. Management of diabetes mellitus, standards of care and clinical practice guidelines. *World Health Organization*.
- Carman, K.L. et al., 2013. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. *Health affairs (Project Hope)*, 32(2), pp.223–31. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/23381514> [Accessed November 15,

2015].

- Carrino, S., Caon, M., Angelini, L., Mugellini, E., Khaled, O. A., Orte, S., ... & Rizzo, G., 2015. A Personalised and Motivational ICT System to Empower Adolescents Towards Healthy Lifestyles. *Innovation in Medicine and Healthcare 2014*, 207, pp.350–359. Available at: <http://ebooks.iospress.nl/publication/38653>.
- Castro, D., 2009. 2009 Atlanta Conference on Science , Technology and Innovation Policy The Role of Information Technology in Medical Research The Role of Information Technology in Medical Research. *Innovation*.
- Celler, B.G., Lovell, N.H. & Basilakis, J., 2003. Using information technology to improve the management of chronic disease. *The Medical journal of Australia*, 179(5), pp.242–246.
- Christie, D. & Channon, S., 2014. The potential for motivational interviewing to improve outcomes in the management of diabetes and obesity in paediatric and adult populations: a clinical review. *Diabetes, obesity & metabolism*, 16(5), pp.381–7. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4237607&tool=pmcentrez&rendertype=abstract>.
- Coleman, M.T. & Newton, K.S., 2005. Supporting self-management in patients with chronic illness. *American family physician*, 72(8), pp.1503–10. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/16273817>.
- Compas, B.E.B. et al., 2012. Coping with chronic illness in childhood and adolescence. *Annual Review of Clinical Psychology*, 8, pp.455–480. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3319320/>.
- Corcoran, N., 2007. Theories and Models in Communicating Health Message. In *Communication Health*. pp. 5–31.
- Costa, E. et al., 2015. Interventional Tools to Improve Prescription and Adherence to Medical Plans. *BioMed research international*.
- Coutu-Nadeau, C., 2014. *Evaluating the Usability of Diabetes Management iPad Applications*.
- Cox, T., 2015. How to Improve Patient Engagement with Cloud Scheduling. Available at: <http://myhealthdirect.com/digital-patient-engagement-tools-improve-patient-adherence/> [Accessed June 30, 2015].
- Cramer, J. a., 2004. A Systematic Review of Adherence With. *Diabetes Care*, 27(August 2003), pp.1218–1224. Available at: <http://care.diabetesjournals.org/content/27/5/1218.full.pdf+html>.
- Crews, R.T. et al., 2013. A growing troubling triad: diabetes, aging, and falls. *Journal of aging research*, 2013, p.342650. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3586503&tool=pmcentrez&rendertype=abstract>.
- Dale, J. et al., 2009. Telephone peer-delivered intervention for diabetes motivation and support: The telecare exploratory RCT. *Patient Education and Counseling*, 75(1), pp.91–98. Available at:

<http://linkinghub.elsevier.com/retrieve/pii/S0738399108005314>.

- Davis Bu, Eric Pan, Janice Walker, Julia Adler-Milstein, David Kenderick, Julie M. Hook, Caitlin M. Cusack, David W. Bates, B.M., 2007. Benefits of Information Technology –Enabled Diabetes Management. *American Diabetes Association*, 30(5), pp.1–6.
- Davis, F.D., 1989. Perceived Usefulness , Perceived Ease Of Use , And User Acceptance. *MIS Quarterly*, 13(3), pp.319–339.
- Dayer, L. et al., 2013. Smartphone medication adherence apps: Potential benefits to patients and providers. *Journal of the American Pharmacists Association*, 53(2), p.172. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3919626&tool=pmcentrez&rendertype=abstract>.
- Deakin, T., 2012. X-PERT structured education programmes improve control in diabetes. *Journal of Diabetes Nursing*, 16(7), pp.266–272.
- Degner, L.F., Sloan, J.A. & Venkatesh, P., 1997. The Control Preferences Scale. *The Canadian journal of nursing research = Revue canadienne de recherche en sciences infirmières*, 29(3), pp.21–43. Available at: <http://europepmc.org/abstract/med/9505581> [Accessed November 27, 2015].
- Delamater, a. M., 2006. Improving Patient Adherence. *Clinical Diabetes*, 24(2), pp.71–77.
- Dellasega, C. et al., 2010. Motivational interviewing to change type 2 diabetes self-care behaviours. *Journal of diabetes nursing*, 14(3), pp.112–118.
- Dexter, P.R. et al., 2010. Preparing for an aging population and improving chronic disease management. *AMIA ... Annual Symposium proceedings / AMIA Symposium. AMIA Symposium*, 2010, pp.162–6. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3041380&tool=pmcentrez&rendertype=abstract>.
- Diabetes, D.O.F., 2009. Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care*, 32(Supplement_1), pp.S62–S67. Available at: <http://care.diabetesjournals.org/cgi/doi/10.2337/dc09-S062>.
- Diabetes, U.K., 2009. Improving supported self-management. , (November).
- Dick, J.J. et al., 2011. Feasibility and usability of a text message-based program for diabetes self-management in an urban African-American population. *Journal of diabetes science and technology*, 5(5), pp.1246–54. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3208889&tool=pmcentrez&rendertype=abstract>.
- Dickey, A., 2012. The Use of Motivational Interviewing by Healthcare Providers to Improve Glycemic Control in Patients with Type 2 Diabetes. *Masters report for MI*.
- Diego Ardigó et al, 2012. Metabo - D4.2.4a: Pilots experience and validation. , p.175.

- Dinneen, S.F., 2008. Structured education for people with type 2 diabetes. *BMJ (Clinical research ed.)*, 336(7642), pp.459–460.
- Dixon, A., 2008. Motivation and Confidence: what does it take to change behaviour? , pp.1–20.
- Dobson, R. et al., 2015. Diabetes Text-Message Self-Management Support Program (SMS4BG): A Pilot Study. *JMIR mHealth and uHealth*, 3(1), p.e32. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4390615&tool=pmcentrez&rendertype=abstract>.
- van der Drift, E. et al., 2014. A remote social robot to motivate and support diabetic children in keeping a diary. *Proceedings of Human-Robot Interaction 2014*, (Figure 1), pp.463–470. Available at: <http://www.esthervanderdrift.com/wp-content/uploads/remote-support.pdf>.
- Edwards, I.R. & Hugman, B., 1997. The Challenge of Effectively Communicating Risk-Benefit Information. *Drug Safety*, 17(4), pp.216–227. Available at: <http://link.springer.com/10.2165/00002018-199717040-00002> [Accessed December 8, 2015].
- Egede, L.E. et al., 2012. Medication Nonadherence in Diabetes: Longitudinal effects on costs and potential cost savings from improvement. *Diabetes Care*, 35(12), pp.2533–2539. Available at: <http://care.diabetesjournals.org/cgi/doi/10.2337/dc12-0572>.
- El-Gayar, O. et al., 2013. Mobile applications for diabetes self-management: status and potential. *Journal of diabetes science and technology*, 7(1), pp.247–62. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3692239&tool=pmcentrez&rendertype=abstract>.
- EndoGoddess, 2014. EndoGoddess Diabetes App. Available at: <http://www.medstartr.com/projects/19-endogoddess-diabetes-app-clinical-trial-fundraiser> [Accessed December 2, 2015].
- Eng, D.S. & Lee, J.M., 2013. Mobile health applications for diabetes and endocrinology. *Pediatric Diabetes*, 14(4), pp.231–238. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837694/pdf/nihms454202.pdf>.
- Erika Gebel Berg, P., 2014. The Artificial Pancreas Aces New Tests. Available at: <http://www.diabetesforecast.org/2014/mar/the-artificial-pancreas-aces.html> [Accessed December 19, 2014].
- Ernst & Young LLP, 2014. *News and analysis of current issues affecting health care providers and payers*, Available at: [http://www.ey.com/Publication/vwLUAssets/EY-health-care-industry-post/\\$FILE/EY-health-care-industry-post-vertical-integration.pdf](http://www.ey.com/Publication/vwLUAssets/EY-health-care-industry-post/$FILE/EY-health-care-industry-post-vertical-integration.pdf).
- European Commission, 2012. *Ageing Report: Europe Needs to Prepare for Growing Older.*,
- European Commission, 2007. White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues. *Office for Official Publications*

of the European Communities.

- European Food Information Council, 2014. *Motivating Behaviour Change*, Available at: <http://www.eufic.org/article/en/expid/Motivating-behaviour-change/>.
- Evert, A.B. et al., 2013. Nutrition Therapy Recommendations for the Management of Adults With Diabetes. *Diabetes Care*, 36(11), pp.3821–3842. Available at: <http://care.diabetesjournals.org/cgi/doi/10.2337/dc13-2042>.
- Fan, L. & Sidani, S., 2009. Effectiveness of Diabetes Self-management Education Intervention Elements: A Meta-analysis. *Canadian Journal of Diabetes*, 33(1), pp.18–26. Available at: <http://www.sciencedirect.com/science/article/pii/S1499267109310059>.
- Faridi, Z., Liberti, L., Shuval, K., Northrup, V., Ali, A., & Katz, D.L., 2008. Evaluating the impact of mobile telephone technology on type 2 diabetic patients' self-management: the NICHE pilot study. *Journal of evaluation in clinical practice*, 14(3), pp.465–469.
- Fischer, H.H. et al., 2012. Care by cell phone: text messaging for chronic disease management. *American Journal of Managed Care*, 18(2), pp.e42–e47. Available at: <http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=22435883>.
- Fogg, B., 2009. A behavior model for persuasive design. *Proceedings of the 4th International Conference on Persuasive Technology - Persuasive '09*, p.1. Available at: <http://portal.acm.org/citation.cfm?doid=1541948.1541999>.
- Fogg, B.J., 2003. *Persuasive Technology: Using Computers to Change what We Think and Do*, Available at: <http://books.google.com/books?id=9nZHbxULMwgC&pgis=1>.
- Forbes, J.M. & Cooper, M.E., 2013. Mechanisms of Diabetic Complications. *Physiological Reviews*, 93(1), pp.137–188. Available at: <http://physrev.physiology.org/cgi/doi/10.1152/physrev.00045.2011>.
- Frampton, S. et al., 2008. Patient-Centred Care Improvement Guide. , p.247. Available at: www.pickerinstitute.org.
- Francis, A., 1856. *The Extant Works of Aretaeus, the Cappadocian*,
- Frank, A., 2002. Impact of chronic illness on the family. *Journal of the Royal Society of Medicine*, 95(1), pp.57–58.
- Frank T. Denton & Byron G. Spencer, 2015. Chronic health conditions: changing prevalence in an aging population and some implications for the delivery of health care services. *The effects of brief mindfulness intervention on acute pain experience: An examination of individual difference*, 1(435).
- Franklin, V. L., Greene, A., Waller, A., Greene, S. A., & Pagliari, C., 2008. Patients' engagement with "Sweet Talk"—a text messaging support system for young people with diabetes. *Journal of Medical Internet Research*, 10(2).
- Free, C. et al., 2013. The Effectiveness of Mobile-Health Technology-Based Health

Behaviour Change or Disease Management Interventions for Health Care Consumers: A Systematic Review. *PLoS Medicine*, 10(1), p.e1001362.

Fry, J.P. & Neff, R.A., 2009. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. *Journal of medical Internet research*, 11(2), p.e16. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2762806&tool=pmcentrez&rendertype=abstract> [Accessed November 7, 2015].

Funnell, M.M. & Anderson, R.M., 2004. Empowerment and Self-Management of Diabetes. *Clinical Diabetes*, 22(3), pp.123–127.

Garbarino, Maurizio, et al., 2014. Acquisition, Empatica E3—A wearable wireless multi-sensor device for real-time computerized biofeedback and data. In *Wireless Mobile Communication and Healthcare (Mobihealth), 2014 EAI 4th International Conference on. IEEE, 2014*. pp. pp. 39–42.

Gatwood, J. et al., 2014. Addressing medication nonadherence by mobile phone: Development and delivery of tailored messages. *Research in Social and Administrative Pharmacy*, 10(6), pp.809–823. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4182163&tool=pmcentrez&rendertype=abstract>.

Gavvani, R.M., Poursharifi, H. & Aliasgarzadeh, A., 2010. Effectiveness of Information-Motivation and Behavioral skill (IMB) model in improving self-care behaviors & Hba1c measure in adults with type2 diabetes in Iran-Tabriz. *Procedia - Social and Behavioral Sciences*, 5(2), pp.1868–1873. Available at: <http://linkinghub.elsevier.com/retrieve/pii/S1877042810017544>.

Giardini, A. et al., 2015. Toward appropriate criteria in medication adherence assessment in older persons: Position Paper. *Aging clinical and experimental research*. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/26630945> [Accessed December 30, 2015].

Gonzalez, J.S. et al., 2008. Depression and diabetes treatment nonadherence: A meta-analysis. *Diabetes Care*, 31(12), pp.2398–2403.

Goodarzi, M. et al., 2012. Impact of distance education via mobile phone text messaging on knowledge, attitude, practice and self efficacy of patients with type 2 diabetes mellitus in Iran. *Journal of Diabetes & Metabolic Disorders*, 11(1), p.10. Available at: <http://www.jdmdonline.com/content/11/1/10>.

Grady, J.L. et al., 2011. Using message framing to achieve long-term behavioral changes in persons with diabetes. *Applied Nursing Research*, 24(1), pp.22–28. Available at: <http://dx.doi.org/10.1016/j.apnr.2009.03.007>.

Graffy, J. et al., 2009. Personalized care planning for diabetes : policy lessons from systematic reviews of consultation and self-management interventions. *Primary Health Care Research and Development*, 10, pp.210–222. Available at: <http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=5878832>.

Green, A.J. et al., 2007. Health-related behaviours of people with diabetes and those with cardiometabolic risk factors: results from SHIELD. *International*

journal of clinical practice, 61(11), pp.1791–7. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2121151&tool=pmcentrez&rendertype=abstract>.

Hall, M., Felton, A. M., Tuomilehto, J., & Hughes, E., 2008. Diabetes-the policy puzzle is Europe making progress. An Audit of Diabetes Services in the EU. London/Brussels: FEND and IDF.

Hamine, S. et al., 2015. Impact of mHealth Chronic Disease Management on Treatment Adherence and Patient Outcomes: A Systematic Review. *Journal of Medical Internet Research*, 17(2), p.e52. Available at: <http://www.jmir.org/2015/2/e52/>.

Hanauer, D.A. et al., 2009. Computerized Automated Reminder Diabetes System (CARDS): e-mail and SMS cell phone text messaging reminders to support diabetes management. *Diabetes technology & therapeutics*, 11(2), pp.99–106. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/19848576>.

Harris, R.E., 2013. *Epidemiology of Chronic Disease*,

Hassenzahl, M., Burmester, M. & Koller, F., 2003. AttrakDiff: A questionnaire to measure perceived hedonic and pragmatic quality. *Mensch & Computer*. Available at: https://scholar.google.it/scholar?q=Hassenzahl%2C+M.%3B+Burmester%2C+M.%3B+Koller%2C+F.+AttrakDiff%3A+A+questionnaire+to+measure+perceived+hedonic+and+pragmatic+quality.+Mensch&btnG=&hl=it&as_sdt=0%2C5#0 [Accessed November 25, 2015].

Haveman-Nies, A., de Groot, L.C.P.G.M. & van Staveren, W. a., 2003. Dietary quality, lifestyle factors and healthy ageing in Europe: The SENECA study. *Age and Ageing*, 32(4), pp.427–434.

Healthcarebusinesstech.com, 2014. Medical Technology. Available at: <http://www.healthcarebusinesstech.com/MEDICAL-TECHNOLOGY/> [Accessed May 7, 2015].

Heart Foundation, 2011. *Interventions to improve your patients ' adherence.*,

Hee, M., 2010. Type 2 Diabetes Mellitus, a review comparing Indigenous and Non-Indigenous Australians. *Medical Student Journal of Australia*, 2(1), pp.15–19.

Heisler M., 2007. Overview of Peer Support Models to Improve Diabetes Self Management and Clinical Outcomes. *Diabetes Spectrum*, 20(4), pp.214–221.

Helal, A., Cook, D.J. & Schmalz, M., 2009. Smart home-based health platform for behavioral monitoring and alteration of diabetes patients. *Journal of diabetes science and technology (Online)*, 3(1), pp.141–148.

Heneghan, C. et al., 2013. Evidence for non-communicable diseases: analysis of Cochrane reviews and randomised trials by World Bank classification. *BMJ Open*, 3(7), p.e003298. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3703573&tool=pmcentrez&rendertype=abstract>.

Hibbard, J.H. et al., 2004. Development of the Patient Activation Measure (PAM):

- conceptualizing and measuring activation in patients and consumers. *Health services research*, 39(4 Pt 1), pp.1005–26. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1361049&tool=pmcentrez&rendertype=abstract> [Accessed September 17, 2015].
- Hilary King & Marian Rewers, 1993. Global Estimates for Prevalence of Diabetes Mellitus and Impaired Glucose Tolerance in Adults. *Diabetes care*.
- Hill, J., Nielsen, M. & Fox, M.H., 2013. Understanding the social factors that contribute to diabetes: a means to informing health care and social policies for the chronically ill. *The Permanente journal*, 17(2), pp.67–72. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3662286&tool=pmcentrez&rendertype=abstract>.
- Hirose, M., Beverly, E. a. & Weinger, K., 2012. Quality of life and technology: Impact on children and families with diabetes. *Current Diabetes Reports*, 12(6), pp.711–720.
- Ho, P.M. et al., 2006. Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. *Archives of internal medicine*, 166(17), pp.1836–41. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/17000939> [Accessed December 5, 2015].
- Hussein, W.I., Hasan, K. & Jaradat, A.A., 2011. Effectiveness of mobile phone short message service on diabetes mellitus management; the SMS-DM study. *Diabetes research and clinical practice*, 94(1), pp.e24–6. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21840079>.
- Hutchison, D. & Mitchell, J.C., 2010. *Persuasive Technology: 5th International Conference, PERSUASIVE 2010, Copenhagen, Denmark, June 7-10, 2010. Proceedings*,
- Hutton, R., 1996. The impact of information technology on condition monitoring. *Bhr Group Conference Series Publication*, 2(22), pp.23–35.
- Ijsselstein, W. et al., 2006. Persuasive Technology for Human Well-Being: Setting the Scene. *Lncs*, 3962, pp.1–5.
- IMAGE Toolkit working group, 2010. *Take action to prevent diabetes. A toolkit for the prevention of type 2 diabetes in Europe*, Available at: <papers2://publication/uuid/6D2543B8-0E16-44B6-948B-5887FA96F07B>.
- Intel Digital Health Group, 2010. *Applying Behavior Change Principles to Remote Health Management: A Primer and Style Guide*, Available at: http://www.intel.com/pressroom/kits/healthcare/HRI_whitepaper.pdf.
- International Diabetes Federation (IDF), 2013. *Managing older people with type 2 diabetes: Global guideline*,
- Inzucchi, S.E. et al., 2012. Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach: Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*, 35(6), pp.1364–1379. Available at: <http://care.diabetesjournals.org/cgi/doi/10.2337/dc12-0413>.

- Iuga, A.O. & McGuire, M.J., 2014. Adherence and health care costs. *Risk Management and Healthcare Policy*, 7, pp.35–44.
- James, J., 2013. Health Policy Brief: Patient Engagement. *Health Affairs*, pp.1–5. Available at: www.healthaffairs.org.
- Jimmy, B. & Jose, J., 2011. Patient medication adherence: Measures in daily practice. *Oman Medical Journal*, 26(3), pp.155–159.
- Johnson, J.A. & Boatman, L.I., 1996. Drug-Related Morbidity and Mortality : A Cost-of-Illness Model. , 2(1), pp.39–47.
- Johnson, S.B., 1992. Methodological issues in diabetes research: measuring adherence. *Diabetes care*, 15(11), pp.1658–1667.
- Johnson-Laird, P. & Oatley, K., 1989. The language of emotions: An analysis of a semantic field. *Cognition and emotion*. Available at: <http://www.tandfonline.com/doi/abs/10.1080/02699938908408075> [Accessed December 3, 2015].
- Joint British Diabetes Societies for Inpatient Care Group, 2012. Self-management of diabetes in hospital. , (March). Available at: <http://www.diabetes.org.uk/Documents/Reports/67190-Self-management-in-hospital0312.pdf>.
- Jonathan Javitt, MD, M., 2014. The Future in Hand | mHealth Technologies Hold Promise for Better Managing Chronic Illness. Available at: <http://www.himss.org/ResourceLibrary/GenResourceDetail.aspx?ItemNumber=32590> [Accessed June 6, 2015].
- Jr, L.J. et al., 2004. Understanding the Environmental Issues in Diabetes Self-Management Education Research : A Reexamination of 8 Studies in Community-Based Settings. *Annals of Internal Medicine*, 140(2), pp.964–971.
- Kadirvelu, A., Sadasivan, S. & Ng, S.H., 2012. Social support in type II diabetes care: A case of too little, too late. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, 5, pp.407–417.
- Kitabchi, A.E. et al., 2006. Hyperglycemic Crises in Adult Patients With Diabetes: A consensus statement from the American Diabetes Association. *Diabetes Care*, 29(12), pp.2739–2748. Available at: <http://care.diabetesjournals.org/cgi/doi/10.2337/dc06-9916>.
- Klaassen, R., op den Akker, R. & op den Akker, H., 2013. Feedback presentation for mobile personalised digital physical activity coaching platforms. *Proceedings of the 6th International Conference on Pervasive Technologies Related to Assistive Environments - PETRA '13*, pp.1–8. Available at: <http://dl.acm.org/citation.cfm?doid=2504335.2504404>.
- Klonoff, D.C., 2009. Using telemedicine to improve outcomes in diabetes--an emerging technology. *Journal of diabetes science and technology (Online)*, 3(4), pp.624–628.
- Krishna, S. & Boren, S.A., 2008. Diabetes self-management care via cell phone: a systematic review. *Journal of diabetes science and technology*, 2(3), pp.509–

17. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2769746&tool=pmcentrez&rendertype=abstract>.
- Krishna, S., Boren, S.A. & Balas, E.A., 2009. Healthcare+Via+Cellphones.pdf. *Telemedicine and e-Health*, 15(3), pp.231–240.
- Kristin A. Riekert, Judith K. Ockene, L.P., 2014. *The Handbook of Health Behavior Change*, Available at: <http://www.scopus.com/inward/record.url?eid=2-s2.0-84923492214&partnerID=tZOtx3y1>.
- Krueger, K.P., Berger, B. a & Felkey, B., 2005. Medication adherence and persistence: a comprehensive review. *Advances in therapy*, 22(4), pp.313–356.
- Laura Hill, Lori W. Turner, S.B.H. and M.P., 2008. Managing Diabetes: Use of the Transtheoretical Model. *Journal of the Arkansas Medical Society*.
- Levy, N., Moynihan, V., Nilo, A., Singer, K., Bernik, L. S., Etiebet, M. A., ... & Natarajan, S., 2015. The Mobile Insulin Titration Intervention (MITI) for Insulin Glargine Titration in an Urban, Low-Income Population: Randomized Controlled Trial Protocol. *JMIR research protocols*, 4(1).
- Li, T. et al., 2011. Education programmes for people with diabetic kidney disease. *Cochrane Database of Systematic Reviews*, (6), p.CD007374. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21678365>.
- Lin, Y. et al., 2011. Motivate: Towards context-aware recommendation mobile system for healthy living. *2011 5th International Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth) and Workshops*, pp.250–253.
- Litan, R., 2008. Vital signs via broadband: Remote health monitoring transmits savings, enhances lives. *Better Health Care Together*. Available at: <http://www.broadbandillinois.org/uploads/cms/documents/litan.pdf>.
- Lopez, H.F. et al., 2009. Extended Health Visibility in the Hospital Environment. *Biodevices 2009: Proceedings of the International Conference on Biomedical Electronics and Devices*, (October 2015), pp.422–425.
- Di Loreto, C., 2003. Validation of a Counseling Strategy to Promote the Adoption and the Maintenance of Physical Activity by Type 2 Diabetic Subjects. *Diabetes Care*, 26(2), pp.1–5.
- Lorig & H, H., 2003. Self-management education: history, definition, outcomes, and mechanisms. *Ann Behav Med*. 2003; 26:1-7., 26((1)), pp.1–7.
- Lyzwinski, L., 2014. A Systematic Review and Meta-Analysis of Mobile Devices and Weight Loss with an Intervention Content Analysis. *Journal of Personalized Medicine*, 4(3), pp.311–385. Available at: <http://www.mdpi.com/2075-4426/4/3/311/>.
- M., B.J. et al., 2011. Multiple-behavior-change interventions for women with type 2 diabetes. *Diabetes Spectrum*, 24(2), pp.75–80. Available at: <http://spectrum.diabetesjournals.org/content/24/2/75.full.pdf+html>

/ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed10&NEWS=N
&AN=2011690856.

MacIntyre, P. et al., 2004. Effects of a 12-month physical activity counselling intervention on glycaemic control and on the status of cardiovascular risk factors in people with Type 2 diabetes. *Diabetologia*, 47(5), pp.821–832. Available at: <http://link.springer.com/10.1007/s00125-004-1396-5>.

Makinen, M. et al., 2000. Inequalities in health care use and expenditures: Empirical data from eight developing countries and countries in transition. *Bulletin of the World Health Organization*, 78(1), pp.55–65.

Mantwill, S. et al., 2015. EMPOWER-support of patient empowerment by an intelligent self-management pathway for patients: study protocol. *BMC Medical Informatics and Decision Making*, 15(1), p.18. Available at: <http://www.biomedcentral.com/1472-6947/15/18>.

Martin, L.R. et al., 2005. The challenge of patient adherence. *Therapeutics and clinical risk management*, 1(3), pp.189–99. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1661624&tool=pmcentrez&rendertype=abstract>.

Mayberry, L.S. & Osborn, C.Y., 2014. Empirical validation of the information-motivation-behavioral skills model of diabetes medication adherence: a framework for intervention. *Diabetes care*, 37(5), pp.1246–53. Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3994934&tool=pmcentrez&rendertype=abstract>.

Mayo Clinic Staff, 2014. Diseases and Conditions Type 2 diabetes - Treatments and drugs. *July 24, 2014*, p.4. Available at: <http://www.mayoclinic.org/diseases-conditions/type-2-diabetes/basics/treatment/con-20031902> [Accessed September 2, 2015].

McCraty, R., Atkinson, M. & Lipsenthal, L., 2000. Emotional self-regulation program enhances psychological health and quality of life in patients with diabetes. ... , CA: *HeartMath Research Center, Institute of* Available at: [/citations?view_op=view_citation&continue=/scholar?hl=en&start=240&as_sdt=0,5&scilib=1&citilm=1&citation_for_view=fp8nlpsAAAAJ:vDZJ-YLwNdEC&hl=en&oi=p](http://citations?view_op=view_citation&continue=/scholar?hl=en&start=240&as_sdt=0,5&scilib=1&citilm=1&citation_for_view=fp8nlpsAAAAJ:vDZJ-YLwNdEC&hl=en&oi=p).

MEDIC8 MANAGER LLC, 2011. Personal caregiver. Smarter tools for better health. Available at: http://www.personalcaregiver.com/about_us.htm [Accessed November 12, 2013].

METABO, 2008. METABO project. European Commission. Information Society Technologies Program. Chronic diseases related to metabolic disorders. ICT-26270. Available at: <http://www.metabo-eu.org>.

Miller, C.K. & Bauman, J., 2014. Goal Setting: An Integral Component of Effective Diabetes Care. *Current Diabetes Reports*, 14(8), p.509. Available at: <http://link.springer.com/10.1007/s11892-014-0509-x>.

Miller, T. a. & DiMatteo, M.R., 2013. Importance of family/social support and impact on adherence to diabetic therapy. *Diabetes, Metabolic Syndrome and*

Obesity: Targets and Therapy, 6, pp.421–426.

- Morandi, A. & Serafin, R., 2007. A personalized motivation strategy for physical activity promotion in diabetic subjects. *Proceedings of the 2nd Workshop on Personalisation for E-Health*, pp.51–55.
- Morrisroe, J., 2014. *Literacy Changes Lives 2014*, Available at: http://www.literacytrust.org.uk/assets/0002/3684/Literacy_changes_lives_2014.pdf.
- Mougiakakou, S.G. et al., 2010. SMARTDIAB: a communication and information technology approach for the intelligent monitoring, management and follow-up of type 1 diabetes patients. *IEEE transactions on information technology in biomedicine : a publication of the IEEE Engineering in Medicine and Biology Society*, 14(3), pp.622–633.
- Mulvaney, S. a. et al., 2012. A pilot test of a tailored mobile and web-based diabetes messaging system for adolescents. *Journal of Telemedicine and Telecare*, 18(2), pp.115–118.
- Nainggolan, L., 2013. Text Messaging Cuts New Diabetes Cases by Almost 40%.
- Nam, S. et al., 2011. Barriers to diabetes management: Patient and provider factors. *Diabetes Research and Clinical Practice*, 93(1), pp.1–9. Available at: <http://dx.doi.org/10.1016/j.diabres.2011.02.002>.
- National eHealth Collaborative, 2012. The Patient Engagement Framework. Available at: <http://www.nationalehealth.org/patient-engagement-framework> [Accessed September 16, 2013].
- National Health Service, 2010. *Emotional and psychological support and care in diabetes*,
- Nes, A.A.G. et al., 2012. The development and feasibility of a web-based intervention with diaries and situational feedback via smartphone to support self-management in patients with diabetes type 2. *Diabetes Research and Clinical Practice*, 97(3), pp.385–393. Available at: <http://linkinghub.elsevier.com/retrieve/pii/S0168822712001532>.
- Network, H.I., 2012. 2012 Healthcare Benchmarks: Diabetes Management. In Patricia Donovan & J. Papay, eds. *2012 Benchmarks in Diabetes Management*. Available at: http://hin.com/chartoftheweek/diabetes_management_challenges.html.
- NíMhurchadha, S., & Sayers, J., 2014. *Modelling Patient Behaviour to Improve Self-Management in Diabetes*, Available at: http://www.pharmaphorum.com/adam-wp-2014/Atlantis_WP_Diabetes_Patient_Insights_Digital_v0-8_FINAL.PDF.
- Norman, D.A. & Draper, S.W., 1986. *User Centered System Design: New Perspectives on Human-Computer Interaction*, L. Erlbaum Associates Inc. Available at: <http://dl.acm.org/citation.cfm?id=576915> [Accessed December 21, 2015].
- Nundy, S. et al., 2013. Developing a behavioral model for mobile phone-based

- diabetes interventions. *Patient Education and Counseling*, 90(1), pp.125–132.
Available at:
<http://linkinghub.elsevier.com/retrieve/pii/S0738399112003813>.
- Nundy, S. et al., 2012. Using mobile health to support the chronic care model: developing an institutional initiative. *International journal of telemedicine and applications*, 2012, p.871925. Available at:
<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3523146&tool=pmcentrez&rendertype=abstract>.
- Office, C.B., 2008. Evidence on the Costs and Benefits of Health Information Technology. *Evidence report Technology Assessment*, 132(May), pp.1–71.
Available at:
<http://www.cbo.gov/ftpdocs/91xx/doc9168/HealthITTOC.2.1.htm>.
- Olmen, J. Van et al., 2014. Motivating better diabetes self-care with SMS text messaging. , 59(June), pp.32–35.
- Omnicell, I., 2014. *The Need for Adherence Pharmacy*,
- op den Akker, H. et al., 2015. Tailored motivational message generation: A model and practical framework for real-time physical activity coaching. *Journal of Biomedical Informatics*, 55, pp.104–115. Available at:
<http://linkinghub.elsevier.com/retrieve/pii/S1532046415000489>.
- Optimism, 2010. OptimismApp. Available at: <http://www.findingoptimism.com/>
[Accessed January 21, 2015].
- Osterberg, L. & Blaschke, T., 2005. Adherence to Medication. , pp.487–497.
Available at:
<http://www.ub.edu/farmaciaclinica/projectes/webquest/WQ2/docs/osterberg.pdf>.
- Painter, J.T., Moore, G. & Morris, B., 2015. Addressing Medication Non-Adherence through Implementation of an Appointment-Based Medication Synchronization Network. *National community pharmacist association*.
- Passa, P., 2002. Diabetes trends in Europe. *Diabetes/metabolism research and reviews*, 18(S3), pp.S3–S8.
- Patnaik, L., Joshi, A. & Sahu, T., 2014. Mobile based intervention for reduction of coronary heart disease risk factors among patients with diabetes mellitus attending a tertiary care hospital of India. *Journal of Cardiovascular Disease Research*, 5(4), pp.28–36. Available at:
<http://www.jcdronline.org/article/413>.
- Pena-Robichaux, V., Kvedar, J.C. & Watson, A.J., 2010. Text messages as a reminder aid and educational tool in adults and adolescents with atopic dermatitis: A pilot study. *Dermatology Research and Practice*, 2010, pp.1–6.
- Peyrot, M. & Rubin, R.R., 2007. Behavioral and Psychosocial Interventions in Diabetes. *Diabetes care*, 30(10), pp.2433–2440.
- Pharmaceuticals, J., 2014. *Assessing the Treatment Barriers for Patients with Type 2 diabetes A care Coordination Tool for Use With Patients*, Available at:

<http://www.janssenpharmaceuticalsinc.com/sites/default/files/pdf/T2D-treatment-barrier-assessment.pdf>.

PharmaGuy, 2012. My POV Regarding Regulation of Pharma Mobile Medical Apps. Available at: http://pharmamkting.blogspot.com.es/2012_10_01_archive.html [Accessed April 7, 2015].

Poretsky, L., 2010. *Principles of Diabetes Mellitus*, Springer Science & Business Media. Available at: <https://books.google.com/books?id=i0qojvF1SpUC&pgis=1> [Accessed December 7, 2015].

Proteus, 2014. Proteus Digital Health. Available at: <http://www.proteus.com/> [Accessed January 18, 2015].

Public Health Institute, ., 2010. The Role Of Information and Communications Technology In Chronic Disease Management The Role Of Information and Communications Technology In Chronic Disease Management Table of Contents. *Center for Innovation and Technology in Public Health (CITPH), USA*, (January).

Quest Diagnostics Incorporated, 2015. My health: secured by my quest. Available at: <https://myquest.questdiagnostics.com/web/appts> [Accessed March 22, 2015].

Quinn, C.C. et al., 2011. Cluster-Randomized Trial of aMobile Phone Personalized Behavioral Intervention for BloodGlucose Control. *Diabetes Care*, 34(September), p.1934–.

Rachmani, R., 2005. Treatment of High-Risk Patients with Diabetes: Motivation and Teaching Intervention: A Randomized, Prospective 8-Year Follow-Up Study. *Journal of the American Society of Nephrology*, 16(3_suppl_1), pp.S22–S26. Available at: <http://www.jasn.org/cgi/doi/10.1681/ASN.2004110965>.

Reports, M.R., 2013. Mobile Health Apps & Solutions Market by Connected Devices, Health Apps, Medical Apps - Global Trends & Forecast to 2018. , p.277. Available at: http://www.researchandmarkets.com/research/8br354/mhealth_apps_and [Accessed September 22, 2015].

Research, K., 2015. *Global Diabetes Drug Market & Pipeline Insight 2015*, Available at: <https://www.bharatbook.com/drugs-market-research-reports-646382/global-diabetes-drug-pipeline-insight.html>.

Research, T.M., 2014. Diabetes Devices and Drugs Market (Devices: Diagnostic & Monitoring and Insulin Delivery Devices, Drugs: Insulin Derivatives, GLP-1 and OADs) - Global Industry Analysis, Pipeline Analysis, Size, Share, Growth, Trends and Forecast 2013 - 2019. Available at: <http://www.transparencymarketresearch.com/diabetes-devices-market.html>.

Research2Guidance The App Market Specialist, 2014. mHealth App Developer Economics 2014. , pp.1–43. Available at: www.mHealthEconomics.com.

- Reviews, S., 2002. Measuring Adherence and Persistence. , 8(3), pp.204–210.
- Riddell, M.C. & Sigal, R.J., 2013. Physical activity, exercise and diabetes. *Can J Diabetes*, 37(6), pp.359–360. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/24321713>.
- Riley, W.T. et al., 2011. Health behavior models in the age of mobile interventions: Are our theories up to the task? *Translational Behavioral Medicine*, 1(1), pp.53–71.
- Rinker, J., 2014. Diabetes and Patient Engagement. Available at: <http://healthcare-executive-insight.advanceweb.com/Features/Articles/Diabetes-and-Patient-Engagement.aspx> [Accessed June 12, 2014].
- Rothman, A. & Salovey, P., 1997. Shaping perceptions to motivate healthy behavior: the role of message framing. *Psychological bulletin*. Available at: <http://psycnet.apa.org/journals/bul/121/1/3/> [Accessed December 6, 2015].
- Ruggiero, L. and J.O.P., 1993. Readiness for change: Application of the Transtheoretical model to diabetes. *Diabetes Spectrum*, (6), pp.21–60.
- Sabaté, E., 2003. *Adherence to long-term therapies: evidence for action*. World Health Organization.,
- Sanco, D.G. et al., 2013. *Making health literacy a priority in EU policy*,
- Sarah, W., Gojka, R., Anders, G., Richard, S., & Hilary, K., 2004. Global Prevalence of Diabetes. *World Health*, 27(5), pp.1047–1053.
- Saudek, C.D., 2002. The Role of Primary Care Professionals in Managing Diabetes. *Clinical DIABETES*, 20(2), pp.65–66.
- Scales, R. & Miller, J.H., 2003. Motivational techniques for improving compliance with an exercise program: skills for primary care clinicians. *Current sports medicine reports*, 2(3), pp.166–172.
- Schechter, C.B. & Walker, E.A., 2002. Improving Adherence to Diabetes Self-Management Recommendations. *Diabetes Spectrum*, 15(3), pp.170–175. Available at: <http://spectrum.diabetesjournals.org/content/15/3/170.full.pdf+html>.
- Schumann, K.P. et al., 2011. Evidence-based behavioral treatments for diabetes: Problem-solving therapy. *Diabetes Spectrum*, 24(2), pp.64–69.
- Senécal, C., Nouwen, A., & White, D., 2000. Motivation and dietary self-care in adults with diabetes: are self-efficacy and autonomous self-regulation complementary or competing constructs? *Health Psychology*, 19(5), p.452.
- Sentcal, C., Nouwen, A. & White, D., 2000. Motivation and Dietary Self-Care in Adults With Diabetes: Are Self-Efficacy and Autonomous Self-Regulation Complementary or Competing Constructs? , 19(5), pp.452–457.
- Services, D. of H. and H., 2006. *Diabetes Self-Management Education Barrier Study*,
- Services, H., 2011. Global Health and Aging. *NIH Publication no 117737*, 1(4), pp.273–277. Available at: <http://links.jstor.org/sici?sici=0095->

- Sharifirad, G. et al., 2007. The Effect of a Health Belief Model Based Education Program for Foot Care in Diabetic Patients Type II in Kermanshah, Iran (2005). *International Journal of Endocrinology and Metabolism*, 2007(Volume 5, Issue 2, Spring), pp.82–90. Available at: <http://endometabol.com/2061.fulltext>.
- Shiva Gopal Reddy, M.S., 2015. Telemedicine Cuts Costs and Improves Outcomes in Chronic Disease Management. Available at: <http://nuviun.com/content/telemedicine-cuts-costs-and-improves-outcomes-in-chronic-disease-management> [Accessed June 18, 2015].
- Siminerio, L.M. et al., 2007. US nurses' perceptions of their role in diabetes care: results of the cross-national Diabetes Attitudes Wishes and Needs (DAWN) study. *The Diabetes educator*, 33(1), pp.152–162.
- Simmons, D., 2001. Personal Barriers to Diabetes Care: Is It Me, Them, or Us? *Diabetes Spectrum*, 14(1), pp.10–12.
- Simon, G.E., 2001. Treating depression in patients with chronic disease: recognition and treatment are crucial; depression worsens the course of a chronic illness. *The Western journal of medicine*, 175(5), pp.292–293.
- Sledd, A., 2014. Applications of Education in Treatment and Recovery. Available at: <http://adamsledd.com/category/first3/> [Accessed February 14, 2015].
- Sokol, M.C. et al., 2005. Impact of medication adherence on hospitalization risk and healthcare cost. *Medical care*, 43(6), pp.521–530.
- Solon, O., 2012. Tictrac makes self-hacking accessible for the masses. Available at: <http://www.wired.co.uk/news/archive/2012-02/10/tictrac-personal-analytics-beta> [Accessed January 6, 2015].
- Solutions, M.H., 2013. Mobile Health Solutions for Diabetes : a Call to Action. , (August), pp.0–9.
- Spanakis, E. G., Chiarugi, F., Kouroubali, A., Spat, S., Beck, P., Asanin, S., ... & Thestrup, J., 2012. Diabetes management using modern information and communication technologies and new care models. *Interactive journal of medical research*, 1(2). Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3626139/>.
- Statistics, C. for H., 2005. *National Vital Statistics System Homepage*, Available at: <http://www.cdc.gov/nchs/nvss.htm>.
- Stewart, K.J., 2004. Exercise training: can it improve cardiovascular health in patients with type 2 diabetes? *British journal of sports medicine*, 38(3), pp.250–252.
- Steyn, K., & Damasceno, A., 2006. Lifestyle and Related Risk Factors for Chronic Diseases. In World Bank Publications, ed. *Disease and mortality in sub-Saharan Africa*. pp. 247–65. Available at: <http://www.ncbi.nlm.nih.gov/books/NBK2290/>.
- Suksomboon, N., Poolsup, N. & Nge, Y.L., 2014. Impact of phone call intervention

- on glycemic control in diabetes patients: a systematic review and meta-analysis of randomized, controlled trials. *PloS one*, 9(2), p.e89207. Available at:
<http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3929650&tool=pmcentrez&rendertype=abstract>.
- Susan C. Hull, 2015. Using technology to engage patients. *American Nurse Today*, p.Vol. 10, N. 9, Pag– 13–14.
- Takenga, C. et al., 2014. An ICT-Based Diabetes Management System Tested for Health Care Delivery in the African Context. *International journal of telemedicine and applications*, 2014, p.437307. Available at: <Go to ISI>://MEDLINE:25136358.
- Tamayo, T. et al., 2014. Diabetes in Europe: An update. *Diabetes Research and Clinical Practice*, 103(2), pp.206–217. Available at:
<http://linkinghub.elsevier.com/retrieve/pii/S0168822713003902>.
- Tan, M.Y. et al., 2011. A brief structured education programme enhances self-care practices and improves glycaemic control in Malaysians with poorly controlled diabetes. *Health education research*, 26(5), pp.896–907. Available at:
<http://her.oxfordjournals.org/content/early/2011/06/29/her.cyr047.full.pdf+html>
<http://www.ncbi.nlm.nih.gov/pubmed/21715653>.
- Tang, T.S. et al., 2012. Sustaining short-term improvements over the long-term: Results from a 2-year diabetes self-management support (DSMS) intervention. *Diabetes Research and Clinical Practice*, 95(1), pp.85–92. Available at:
<http://linkinghub.elsevier.com/retrieve/pii/S016882271100180X>.
- The HLS-EU Consortium, 2012. *The European Health Literacy Project: Final Report*,
- Thorpe, K.E. & Howard, D.H., 2006. The Rise In Spending Among Medicare Beneficiaries: The Role Of Chronic Disease Prevalence And Changes In Treatment Intensity. *Health Affairs*, 25(5), pp.w378–w388. Available at:
<http://content.healthaffairs.org/cgi/doi/10.1377/hlthaff.25.w378>.
- Thrower, C., 2015. *Recipe for Life-Health Awareness*,
- Tidy, C., 2010. *Diabetes Education and Self-management Programmes.*, Available at:
www.patient.co.uk/doctor/diabetes-education-and-self-management-programmes.
- Tran, J., Tran, R. & White, J.R., 2012. Smartphone-based glucose monitors and applications in the management of diabetes: An overview of 10 salient “apps” and a novel smartphone-connected blood glucose monitor. *Clinical Diabetes*, 30(4), pp.173–178.
- Tripp-Reimer, T. et al., 2001. Cultural Barriers to Care: Inverting the Problem. *Diabetes Spectrum*, 14(1), pp.13–22. Available at:
<http://spectrum.diabetesjournals.org/content/14/1/13.full.pdf+html>.
- Uggiero, L.A.R. & Reese, G.E.G., 2003. Stages of Change for Healthy Eating in Diabetes. *Diabetes Care*, 26(5), pp.1468–1474.

- Un Population Division, 2012. World Population Prospects: the 2010 Revision. *Waste Management Research*, 27(8), pp.800 –812. Available at: <http://esa.un.org/unpd/wpp/index.htm>.
- Vaccaro, J.A. et al., 2014. The Role of Family/Friend Social Support in Diabetes Self-Management for Minorities with Type 2 Diabetes. *World Journal of Nutrition and Health*, 2(1), pp.1–9. Available at: <http://pubs.sciepub.com/jnh/2/1/1/index.html>.
- Venkatesh, V., Thong, J.Y.L. & Xu, X., 2012. Consumer Acceptance and Use of Information Technology: Extending the Unified Theory. *MIS Quarterly*, 36(1), pp.157–178.
- Vogeli, C. et al., 2007. Multiple Chronic Conditions: Prevalence, Health Consequences, and Implications for Quality, Care Management, and Costs. *Journal of General Internal Medicine*, 22(S3), pp.391–395. Available at: <http://link.springer.com/10.1007/s11606-007-0322-1>.
- WHO, 2014. *Global status report on noncommunicable diseases 2014*,
- Wientjens, W., 2008. Peer support in diabetes management – time for a change. , 53(3), pp.45–47.
- Williams, G. C., Lynch, M., & Glasgow, R.E., 2007. Computer-assisted intervention improves patient-centered diabetes care by increasing autonomy support. *Health Psychology*, 26.6: 728.
- Zgibor, J.C. & Songer, T.J., 2001. External Barriers to Diabetes Care: Addressing Personal and Health Systems Issues. *Diabetes Spectrum*, 14(1), pp.23–28.
- ZYTO Corp, 2015. ZYTO. Available at: <https://www.zyto.com/> [Accessed June 2, 2015].

Publications related with the research work

- Fioravanti, a., Fico, G., Arredondo, M. T., Salvi, D., & Villalar, J. L. (2010). Integration of heterogeneous biomedical sensors into an ISO/IEEE 11073 compliant application. 2010 Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBC'10, 1049–1052. <http://doi.org/10.1109/IEMBS.2010.5628086>
- Fico, G., Fioravanti, A., Arredondo, M. T., Ardigó, D., & Guillén, A. (2010). A healthy lifestyle coaching-persuasive application for patients with type 2 diabetes. In Conference proceedings : Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual Conference (Vol. 2010, pp. 2221–4). <http://doi.org/10.1109/IEMBS.2010.5626185>
- Fico, G., Fioravanti, A., Arredondo, M. T., Leuteritz, J.-P., Guillén, A., & Fernandez, D. (2011). A user centered design approach for patient interfaces to a diabetes IT platform. Conference Proceedings : Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Conference, 2011, 1169–72. <http://doi.org/10.1109/IEMBS.2011.6090274>
- Fioravanti, a., Fico, G., Arredondo, M. T., & Leuteritz, J. P. (2011). A mobile feedback system for integrated E-health platforms to improve self-care and compliance of diabetes mellitus patients. Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS, 3550–3553. <http://doi.org/10.1109/IEMBS.2011.6090591>
- González, A., Fico, G., Arredondo, A., & Fioravanti, A. (2011). An iPhone-based application for promoting type 2 diabetic patients self- management towards healthy lifestyle habits. In Conference proceedings : Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Conference (pp. 6–9). Retrieved from http://oa.upm.es/13234/2/INVE_MEM_2011_110893.pdf
- Zarkogianni, K., Mitsis, K., Fioravanti, A., & Nikita, K. S. (2014). Neuro - Fuzzy based Glucose Prediction Model for Patients with Type 1 Diabetes Mellitus. In Biomedical and Health Informatics (BHI), 2014 IEEE-EMBS International Conference on (pp. 252–255). IEEE. (pp. 252–255).
- Fico, G., Fioravanti, A., Arredondo, M. T., Gorman, J., Diazzi, C., Arcuri, G., ... & Pirini, G. (2014). Integration of Personalized Healthcare Pathways in an ICT platform for Diabetes Management: a small-scale exploratory study. IEEE J Biomed Health Inform.
- Fico, G., Fioravanti, A., Arredondo, M. T., Diazzi, C., Arcuri, G., & Conti, C. (2014). Adaptive Healthcare Pathway for Diabetes Disease Management. In Springer International Publishing (Ed.), XIII Mediterranean Conference on Medical and Biological Engineering and Computing 2013 (pp. 1468–1472).

- Fico, G., Fioravanti, A., Arredondo, M., Gorman, J., Diazzi, C., Arcuri, G., Pirini, G. (2014). Integration of Personalized Healthcare Pathways in an ICT platform for Diabetes Management: a small-scale exploratory study. *IEEE Journal of Biomedical and Health Informatics*. <http://doi.org/10.1109/JBHI.2014.2367863>
- Fioravanti, A., Fico, G., Salvi, D., García-Betances, R. I., & Arredondo, M. T. (2015). Automatic messaging for improving patients engagement in diabetes management: an exploratory study. *Medical & Biological Engineering & Computing*, 1–10. <http://doi.org/10.1007/s11517-014-1237-8>
- Zarkogianni, K., Mitsis, K., Litsa, E., Arredondo, M.-T., Fico, G., Fioravanti, A., & Nikita, K. S. (2015). Comparative assessment of glucose prediction models for patients with type 1 diabetes mellitus applying sensors for glucose and physical activity monitoring. *Medical & Biological Engineering & Computing*, 1–11. <http://doi.org/10.1007/s11517-015-1320-9>
- Zarkogianni, K., & Nikita, K. S. (2015). Special issue on emerging technologies for the management of diabetes mellitus. *Medical & Biological Engineering & Computing*, 53(12), 1255–1258. <http://doi.org/10.1007/s11517-015-1422-4>

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The following annexes are providing detailed information on some of the instruments that were used to conduct the research work.

Annexes

A.1 METABO Evaluation Survey + EBF perceived usefulness – Caregivers

		I totally disagree	I rather disagree	I partly agree	I rather agree	I totally agree
01	The information about the patients' behaviour and health status always seemed to be correct and plausible	☐	☐	☐	☐	☐
02	METABO ensures that professionals never miss any important information	☐	☐	☐	☐	☐
03	The Medical Panel provides a lot of unnecessary information about the patients	☐	☐	☐	☐	☐
04	METABO ensures that patients never miss any important information	☐	☐	☐	☐	☐
05	The Medical Panel provides information about the patients in a way that does not annoy me unnecessarily	☐	☐	☐	☐	☐
06	The Medical Panel should inform me more actively about a problematic status or behaviour of one patient	☐	☐	☐	☐	☐

Please indicate how much you agree on the following affirmations, using the first five options. If you do not know any of the functions, check the option on the far right.

		I totally disagree	I rather disagree	I partly agree	I rather agree	I totally agree	I don't know this feature
07	I find the compliance table, which tells me how well the patients use the EBF system, very useful	☐	☐	☐	☐	☐	☐
08	I find the messages table, which shows how often the patients receive alert messages, very useful	☐	☐	☐	☐	☐	☐
09	I find the diagnostic information, available on the "clinical data" tab, very useful	☐	☐	☐	☐	☐	☐

A.2 EBF perceived Usefulness – Patients

Please give us your evaluation about the utility and the quality of the messages sent to you on your device. This includes both, messages from the medical doctor and messages from the system.

		I totally disagree	I rather disagree	I partly agree	I rather agree	I totally agree
01	The messages sent to me have helped me improve my health	☐	☐	☐	☐	☐
02	The messages sent to me reflect my true health status	☐	☐	☐	☐	☐
03	The messages sometimes request me to do something that I cannot or will not do	☐	☐	☐	☐	☐
04	Many messages were so silly that I ignored them	☐	☐	☐	☐	☐
05	The messages did not help me follow my medical prescription better than before	☐	☐	☐	☐	☐
06	Without the automated messages, I would not have fought this way to reach my goals	☐	☐	☐	☐	☐
07	Sent me too many useless messages	☐	☐	☐	☐	☐
08	Many feedback messages are too annoying	☐	☐	☐	☐	☐
09	During the past weeks, I often felt insecure about my health condition and what I should do about it	☐	☐	☐	☐	☐
10	During the past weeks, I have frequently forgotten to do important things about my health	☐	☐	☐	☐	☐

A.3 METABO Perceived Usefulness

		I totally disagree	I rather disagree	I partly agree	I rather agree	I totally agree
01	Using the system would allow me to spend less time with managing my diabetes	0	0	0	0	0
02	Using the system would improve my health	0	0	0	0	0
03	Using the system would increase efficiency in dealing with my diabetes	0	0	0	0	0
04	Using the system, in my job would enhance my effectiveness dealing with my diabetes	0	0	0	0	0
05	Using the system, would make it easier to deal with my diabetes	0	0	0	0	0
06	I would find the system useful in my health management	0	0	0	0	0

A.4 Assessment of knowledge topic importance

		Not at all important to me	Rather not im- portant to me	Partly im- portant to me	Rather important to me	Very im- portant to me
01	Knowledge about diabetes in general (basics, treatments, lifestyle) is ...	0	0	0	0	0
02	Knowledge about hypoglycaemia and hyperglycaemia (causes, symptoms, consequences) is ...	0	0	0	0	0
03	Knowledge about complications and comorbidities is ...	0	0	0	0	0
04	Knowledge about the glycaemia monitoring and insulin preparation is ...	0	0	0	0	0
05	Knowledge about diabetic diet is ...	0	0	0	0	0
06	Knowledge about physical activity for diabetic patients is ...	0	0	0	0	0
07	Knowledge about pregnancy management for diabetic patients is ...	0	0	0	0	0
08	Knowledge about Diabetes Management while travelling is ...	0	0	0	0	0

A.5 Appraisal of Diabetes Scale

		Not at all	Rather not	More or less	Rather yes	Totally
01	How upsetting is having diabetes for you?	0	0	0	0	0
02	How much control over your diabetes do you have?	0	0	0	0	0
03	How much uncertainty do you currently experience in your life as a result of being diabetic?	0	0	0	0	0
04	How likely is your diabetes to worsen over the next several years? (...personal feeling ...)	0	0	0	0	0
05	Do you believe that achieving good diabetic control is due to your efforts as compared to factors which are beyond your control?	0	0	0	0	0
06	How effective are you in coping with your diabetes?	0	0	0	0	0
07	To what degree does your diabetes get in the way of your developing life goals?	0	0	0	0	0

A.6 Adoption of good practices

		Not at all	Rather not	More or less	Rather yes	Totally
01	To what degree are you willing to better manage your treatment?	0	0	0	0	0
02	To what degree are you willing to better manage your alimentation?	0	0	0	0	0
03	To what degree are you willing to stabilize your weight?	0	0	0	0	0
04	To what degree are you willing to Increase physical exercise?	0	0	0	0	0
05	To what degree are you willing to stabilize your glycaemia?	0	0	0	0	0
06	To what degree are you willing to avoid diabetes complications?	0	0	0	0	0

Adoption of good practices-Actual

		Not at all	Rather not	More or less	Rather yes	Totally
01	I followed medical prescriptions and advices much better	0	0	0	0	0
02	I have better control over my weight	0	0	0	0	0
03	I did more physical exercise	0	0	0	0	0
04	I have eaten in a more "well-balanced" way	0	0	0	0	0
05	I better managed glycaemia	0	0	0	0	0

A.7 AttrakDiff questionnaire

		Totally wrong	Rather wrong	More or less correct	Rather correct	Totally correct
01	This system thinks the way I do.	☐	☐	☐	☐	☐
02	This system speaks my language.	☐	☐	☐	☐	☐
03	There are a lot of misunderstandings between me and this system.	☐	☐	☐	☐	☐
04	The communication between me and this system works very well.	☐	☐	☐	☐	☐

Following, are pairs of words to assist you in your evaluation. Each pair represents extreme contrasts. The possibilities between the extremes enable you to describe the intensity of the quality you choose.

An example:

disagreeable ☐ ☐ ☐ ☐ ☒ ☐ ☐ likeable

This evaluation tells us that the product is predominantly likable, but that there is marginal room for improvement.

Do not spend time thinking about the word-pairs. Try to give a spontaneous response. You may feel that some pairs of terms do not adequately describe the product. In this case please still be sure to give an answer. Keep in mind that there is no right or wrong answer. Your personal opinion is what counts!

human	☐	☐	☐	☐	☐	☐	☐	technical
isolating	☐	☐	☐	☐	☐	☐	☐	connective
pleasant	☐	☐	☐	☐	☐	☐	☐	unpleasant
inventive	☐	☐	☐	☐	☐	☐	☐	conventional
simple	☐	☐	☐	☐	☐	☐	☐	complicated

professional	☐	☐	☐	☐	☐	☐	☐	unprofessional
ugly	☐	☐	☐	☐	☐	☐	☐	attractive
practical	☐	☐	☐	☐	☐	☐	☐	impractical
likeable	☐	☐	☐	☐	☐	☐	☐	disagreeable
cumbersome	☐	☐	☐	☐	☐	☐	☐	straightforward
stylish	☐	☐	☐	☐	☐	☐	☐	tacky
predictable	☐	☐	☐	☐	☐	☐	☐	unpredictable
cheap	☐	☐	☐	☐	☐	☐	☐	premium
alienating	☐	☐	☐	☐	☐	☐	☐	integrating
brings me closer to people	☐	☐	☐	☐	☐	☐	☐	separates me from people
unpresentable	☐	☐	☐	☐	☐	☐	☐	presentable
rejecting	☐	☐	☐	☐	☐	☐	☐	inviting
unimaginative	☐	☐	☐	☐	☐	☐	☐	creative
good	☐	☐	☐	☐	☐	☐	☐	bad
confusing	☐	☐	☐	☐	☐	☐	☐	clearly structured
repelling	☐	☐	☐	☐	☐	☐	☐	appealing
bold	☐	☐	☐	☐	☐	☐	☐	cautious
innovative	☐	☐	☐	☐	☐	☐	☐	conservative
dull	☐	☐	☐	☐	☐	☐	☐	captivating
undemanding	☐	☐	☐	☐	☐	☐	☐	challenging
motivating	☐	☐	☐	☐	☐	☐	☐	discouraging

novel	o	o	o	o	o	o	o	ordinary
unruly	o	o	o	o	o	o	o	manageable

A.8 AFM Library

The following tables describe in detail the AFM message structure used during the randomized controlled pilot. The text content of the messages was validated by clinical and psychologist professionals.

1.1.1 Nutrition Table

ID	Level	Topic	Segment	Type	Stage	AFM message	Condition	Trigger
NU_L1_001	1	1-Reminder for eating or registering breakfast	1, 2, 3	1, 2	3,4,5	"Did you have your breakfast?"	Conditions: a) pre-set breakfast time 7.00am-7.45am, b) no info was provided for breakfast	After 1 hour. Ex: It is 8am (or after 8am if the patient has just logged on to PMD)
NU_L1_002	1	2-Reminder for eating or registering lunch	1, 2, 3, 6	1, 2	3,4,5	"Did you have your lunch?"	Conditions: a) pre-set lunch time 12.00am-01.45pm, b) no info was provided for lunch	After 2 hours: Ex: It is 2pm (or after 2pm-the patient just logged on to the PMD)
NU_L1_003	1	3-Reminder for eating or registering dinner	1, 2, 3	1, 2	3,4,5	"Did you have your dinner?"	Conditions: a) pre-set dinner time 7.00pm-8.45pm, b) no info was provided for dinner	After 2 hours: Ex: It is 9pm (or after 9pm-the patient just logged on to PMD)
NU_L1_004	1	4-Reminder for eating too much/few CHO	1, 2, 3, 4, 5, 6	1, 2	3,4,5	"Are you sure you want to eat much more/less CHO that your prescription?"	More/less than 30% of quantity prescribed	Button is pressed to inform PMD s/he is going to eat

NU_L1_05	1	5-Reminder for eating too much/few Kcal	1, 2, 3, 4, 5, 6	1, 2	3,4	"Are you sure you want to eat much more/less Kcal that your prescription?"	More/less than 50% of quantity prescribed	Button is pressed to inform PMD s/he is going to eat
NU_L2_06	2	6-Recommendation for not following correctly the food intake prescription	3, 4, 5, 6	1, 2	3,4	"You have not followed correctly your diet prescription in the last week, please revise your food intake graphic tool and your diet educational content"	Patient is not following correctly the food intake prescription in the last week	After 7 days of evaluation
NU_L1_07	1	7-Long distance car travel_01 (related to new added event "travel")	1, 2,3	1, 2	3,4	"As soon as you arrive, check where you can get an afterhours meal/quick bite" OR "Check your glucose level twice as regularly"	Event - long distance car travel	Button is pressed to inform PMD s/he is going to travel
NU_L1_08	1	8-Long distance car travel_02 (related to new added event "travel")	1, 2, 3	1, 2	3,4,5	"Have easily digestible and immediate effect CHOs available"	Related to new added event "travel"	Button is pressed to inform PMD s/he is going to travel
NU_L3_09	3	9-Patient recorded a higher calorie meal than recommended. PMD recommends staying away from a big dinner	1, 2, 6	1, 2	3,4,5	"You should consume food of no more than xxx calories for the rest of the day" OR "Please eat light	Conditions: a) dietary restrictions based on patient profile data or not b) patient recording a high Kcal meal	Calories intake out of recommended diet in 2 previous meals (> or < to 30% of the FI

						till bed-time (up to xxx Kcal)" OR " You should have a light dinner to-night"			pre-scription in the previous meal)
NU_L3_010	3	10-Eat adequate amount of CHO according to the quantity of administered insulin	1, 2, 3, 4, 5	1, 2	3,4	"Eat adequate amount of CHO according to the quantity of administered insulin"		CHO intake out of range according to insulin dose	If CHO is > or < to 50% of the FI prescriptions
NU_L3_011	3	11-Rich fibres diet	1, 2, 3, 4, 5, 6	2	3,4	"Eat the correct amount of fibres"		General	
NU_L3_012	3	12-Related to new added event "travel"	1, 2,3	1	3,4,5	"Do not skip meals- while travelling you need all the energy you can get"		Button is pressed to inform PMD s/he is going to travel	After a "trip" selection
NU_L3_013	3	13-Related to new added event "travel"	1, 2,3	1	3,4,5	"Be extra cautious- Travelling overseas changes your bio-rhythm and thus metabolic response"		Button is pressed to inform PMD s/he is going to travel	After a "trip" selection
NU_L3_014	3	14-Lack of motivation-motivational message	1, 2,3	2	3,4	"Have a good breakfast and jump start your day!"		-	Before the breakfast
NU_L3_015	3	15-NU-Tip	1, 2,3	2	3,4	"You need to take care of your diet and you will feel better"		-	Before a meal
NU_L3_016	3	16-NU-Tip	1, 2, 3, 4, 5, 6	1, 2	3,4	"Eat according to your health needs and		-	Before a meal

						it will pay off!"		
NU_L3_017	3	17-NU-Tip	1, 2, 3, 4, 5, 6	1, 2	3,4	"Your diabetes creates restrictions as to the types of foods you can eat. But think about the thousands of people who die of hunger everyday"	-	Before a meal

1.1.2 Medication Table

ID	Level	Topic	Segment	Type	Stage	AFM message	Condition	Trigger
ME_L1_001	1	Reminder for taking the medication in the short term	3,4,5,6	1, 2	3, 4	"Did you take your "xyz" medication?"	after pre-set time for drug intake (derived from patient setting profile)	It is 9.15am (or after 9.15am-because the patient just logged on to PMD) and the drug intake was set to 9:00 am
ME_L2_002	2	Reminder for taking the medication in the long term	3,4,5,6	1, 2	3, 4	"Did you take all your "xyz" medication in the last week?"	Seven days without introducing all drug intake information	It is 9.15am (or after 9.15am-because the patient just logged on to PMD) and the drug intake was set to 9:00 am
ME_L1_003	1	Reminder for taking his/her insulin dose	3,4,5,6	1, 2	3, 4	"Did you take your insulin dose? If yes, please notify the system"	a) patient indicated he/she will eat b) insulin intake has not been indicated	5 min have passed since indication s/he will eat
ME_L3_004	3	Lack of motivation-motivational messages for people who need them	4	2	3, 4	"Regularly taking your medication stabilizes your condition"	The patient is a non-conforming patient	Every 7 days

ME_L3_005	3	Applies to non-conforming patients	4	1, 2	3, 4	"Your medications helps you have better health and thus a better life"	The patient is a non-conforming patient	Every 7 days
ME_L3_006	3	Generic motivational message	4	2	3, 4, 5	"Your insulin intake keeps your metabolism going- don't forget to take it!"	-	Every 7 days
ME_L3_007	3	Generic motivational message	4	2	3, 4, 5	"Your medication is a burden- but how lucky you are that you can afford to have it"	-	Every 7 days
ME_L3_008	3	Values of target of medication	1,2,3,4, 5,6	1, 2	4, 5	"You should maintain your glycaemic level target: <130 before and <180 after meals"	-	Every 7 days

1.1.3 Physical Exercise Table

ID	Level	Topic	Segment	Type	Stage	AFM message	Condition	Trigger
PA_L2_001	2	Reminder for playing physical activity	1,2,3,4, 5,6	1, 2, 3	3, 4, 5	"Did you have your physical activity in the last week?"	1 week after physical activity module inactivity	No physical activity event entry when expected
PA_L2_002	2	Reminder for playing correctly the physical activity	1,2,3,4, 5,6	1, 2, 3	3, 4, 5	"You should increase your physical	a) If daily steps are < prescribed steps; b) week average < 1.8 METS/day	After 3 days of evaluation

						activity, please check your pre- scription"			
PA_L 2_00 3	2	Reminder for playing correctly the physical activity	1,2,3,4, 5,6	1, 2, 3	4, 5	"You should follow correctly your physical activity prescrip- tion, please revise your physical activity graphic tool and your re- lated physical activity educa- tional content"		Patient is not fol- lowing correctly the physical activ- ity prescription in the last week	After 7 days of evalua- tion
PA_L 2_00 4	1, 2	Education on foot care	2	1, 2, 3	3, 4, 5	"Check your foot carefully after ex- ercise"		Starting exercise (1 time every 3)	Button is pressed to inform PMD s/he is going to ex- ercise
PA_L 1_00 5	1	Drink dur- ing and af- ter the ex- ercise	2	1, 2, 3	3, 4, 5	"Did you take a water bottle with you?"		Starting exercise (1 time every 3)	OK button of Physical Exercise

1.1.4 Glycaemic Level Table

ID	Level	Topic	Seg- ment	Type	Stage	AFM message		Condition	Trigger
GL_L 1_00 1	1	Check gly- caemic level (if pa- tient is al- ready in Hypo)	1,2,3,4, 5,6	1, 2, 3	3, 4	"Check your gly- caemic level"		15 minutes after measurement < 100 mg/dl	No further glucose measure- ment entry
GL_L 1_00 2	1	You have not com- pleted X(number of prescrip-	3,4,5	1, 2, 3	3, 4	"Check your gly- caemic level"		< X glycaemia self- checks in a day	

		tions) glycaemia self-checks							
GL_L1_003	1	Given that the patient indicated his/her intention to exercise and according to the "What-if-advisor", the patient is advised to not exercise	2	1, 2, 3	3, 4, 5	"Please make an extra measurement"		a) there is a low measurement and b) Patient indicated intention to go exercise	OR 15 min have passed since patient indicated had a snack
GL_L1_004	1	Patient should have measurement <XX mg/dl (depending of prescription) glucose value before meals.	1,2,3,4, 5,6	1	3, 4, 5	Your before meal glycaemic level should be <XX. Remember to follow your prescription.		glucose value > XX mg\dl	Patient inform PMD of his/her glycaemic level before meal
GL_L1_005	1	Patient should have glucose value <180mg/dl 2 hours after a meal and on-wards.	1,2,3,4, 5,6	1	3, 4, 5	Your after meal glycaemic level should be <180. Remember to follow your prescription.		>180mg/dl	Patient inform PMD of his/her glycaemic level 2 h after meal

1.1.5 Weight Analysis Table

ID	Level	Topic	Segment	Type	Stage	AFM message		Condition	Trigger
WE_L2_001	2	Reminder for measuring the body weight	1,2,3,4, 5,6	1,2	3, 4, 5	"Did you measure your weight in the last week? If yes, please provide the related information"		No weight data entry when expected	1 week after weight module inactivity

1.1.6 Educational Knowledge Table

ID	Level	Topic	Segment	Type	Stage	AFM message		Condition	Trigger
ED_L2_001	2	Reminder for using Quiz application	1,2,3,4,5,6	1,2,3	3, 4, 5	"Remember to increase your education; do you want to make a Quiz now?"		1 week after Quiz module inactivity	No Quiz data entry when expected

1.1.7 Blood Pressure Analysis Table

ID	Level	Topic	Segment	Type	Stage	AFM message		Condition	Trigger
BP_L2_001	2	Reminder for measuring the blood pressure	1,2,3,4,5,6	1,2,3	3, 4, 5	"Did you measure your blood pressure in the last week? If yes, please provide the related information"		1 week after blood pressure module inactivity	No blood pressure entry when expected

1.1.8 Goal Table

ID	Level	Topic	Segment	Type	Stage	AFM message		Condition	Trigger
GL_L2_001	4	A new goal has been assigned	1,2,3,4,5,6	1,2,3	3, 4, 5	"Your goal has been assigned, please go to check it and start this new challenge!"		Patient has just accepted to achieve a goal	message coming from Control Panel
	4	A pre-set goal has been modified	1,2,3,4,5,6	1, 2, 3	3, 4, 5	"Your goal has been modified, please go		Patient has just accepted to modified his/her goal	message coming from Control Panel

						to check it"			
	4	Fulfilment of a goal	1,2,3,4,5,6	1, 2,, 3	3, 4, 5	"Congratulations! You have achieved your goal!!"		Patient has completed his/her goal	message coming from Control Panel
	4	Notice for approaching the goal	1,2,3,4,5,6	1, 2, 3	3, 4, 5	"Very good! You are near to reach the goal! Keep going like that!"		Patient is near to completed his/her goal	2 weeks before
	4	Recommendation if patient is not following correctly goal prescriptions	1,2,3,4,5,6	1, 2, 3	3, 4, 5	"It is important to follow strictly your prescription in order to not drifting away from your goal"		Patient is drifting away from his/her goal	Check every 2 weeks
	4	Notification for following correctly the goal prescription	1,2,3,4,5,6	1, 2, 3	3, 4, 5	"You are very well following your prescriptions for achieving your goal, check your goal current status now!"		Patient is well get going to achieve the goal	Check every 2 weeks

A.9 Use Cases

Patient description

The diabetic patient who will use the system is basically a T1DM or T2DM with the following characteristics:

- Compliance to doctor's advices
- Willingness to achieve and maintain the main "locus of control" on the disease management; in other words to be the main actor in the disease management process
- Presence of a specific problem affecting glucose control, which may be the lack of adequate metabolic levels despite an optimal treatment or, independently of the current metabolic control, the presence of specific causes of instability, like a current/ coming change in the environment, the need for an intense physical activity training or the presence of significant comorbidities.
- Capacity of learning how to use the system from the patient's end
- Capacity to cope with greater efforts in disease management, like wearing a continuous glucose measurement system, recording food intake, recording drug intake, etc.

More in general, two major patient's profiles are identified:

Profile 1

This patient needs to increase the understanding of which factors in his/her normal life interfere with glucose control in order to cope with his/her specific needs in terms of treatment and lifestyle without major, unrealistic changes. This type of patient has a bad metabolic control either because of inexplicable reasons or because of a major temporary/ chronic reason, despite the best available treatment without METABO.

The most important issue for the patient is to understand his/her personal interaction among food, insulin, exercise, and other changes in lifestyle or in metabolic response to treatment.

Profile 2

This patient may have a good metabolic control but he/ she is not able to identify the occurrence of a hypoglycaemic episode. Therefore, the patient is exposed to the risk of major neurological complications of hypoglycaemia (seizures, and sudden loss of consciousness) without any preliminary symptom or with a too quick establishment of symptoms.

The most important issue for this patient is to be supported by a non-invasive alerting system able to warn the patient in case of onset of hypoglycaemia.

The patient interacts with the system basically through a PMD which provides a browsable graphical user interface to access all the care plan adherence's related data.

The following section present four of the use cases defined within the EBF design and development phases. The uses cases describe three examples of how the patient interacts with the PMD when receiving an AFM and one example involving the professional.

Patient Use Cases

The presented models are based on current information and findings provided by pilots.

1. Patient Alert

Use Case n°	1
Title	The patient is alerted by PMD
Actor	Patient
Steps	<div>1 Patient receives an AFM-Warning from the PMD</div> <div>2 The patient acknowledges having received the alert</div>
Pre-Condition	PR.1
Description	The AFM-Warning have been enabled in the settings
Post-Condition	PO.1

Description	The patient acknowledges the AFM
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The scheme of Use Case 1 is shown in Figure 125.

Figure 125. Use Case 1: Patient is alerted by the PMD

2. Reminders

Basic Flow of Use Case n°	3
Title	The patient receives an AFM-reminder
Actor	Patient
Description	Patient receives one or more reminders from the PMD on following prescriptions (according to educational topics that are already stored in the PMD) and thus we can measure treatment adherence

Steps	
1	The device notifies either by a buzzer (audio notification) the patient and/or displays a textual message for a reminder
2	The patient confirms that he has been aware of the reminder
3	The patient reads the reminder
4	(optional) Patient rejects the reminder or patient accepts (validates as useful) the reminder and optionally goes to step 6
5	(optional) Patient informs that he has followed or will follow the reminder
Pre-Condition	PR.1
Description	The data entry/review application may be activated but the application should be already in the sensor acquisition mode.
Post-Condition	PO.1
	Returns to the previous screen
Title	The patient confirmation is pending
Description	The patient has not confirmed that he has read the reminder

1

The patients receives periodically an audio notification for the pending message

Use Case 3 is shown in Figure 126.

Figure 126. Use Case 3: Patient receives a reminder

Professional Use Cases

3. Medical Panel

Use Case nº	3
Title	The professional checks information on glycaemic levels
Actor	Professional
Description	The professional checks information related to glycaemic levels for a patient
Steps	

1	The professional clicks on the glycaemic levels icon in the medical panel
2	The professional chooses the type of view for the data (table / graph)
3	The professional closes the application
Pre-Condition	PR.1
Description	Glycaemic levels related information has been transferred to the system and downloaded to the Medical Panel
Pre-Condition	PR.2
Description	The professional has signed in the Medical Panel
Post-Condition	PO.1
Description	Information checked changes status as “checked”
Sub-Flow nº	3.1
Title	The professional checks information on glycaemic levels
Description	The professional checks information related to glycaemic levels
Steps	

1	The professional clicks on the glycaemic level icon in the medical panel
2	The professional chooses glycaemic level information
3	The professional closes the application
Sub-Flow nº	3.2
Title	The professional checks information on glycaemic level in relation to other parameters
Description	The professional checks information related to glycaemic level in relation to other parameters: nutrition and physical exercise
Steps	
1	The professional clicks on the glycaemic level icon in the medical panel
2	The professional chooses several categories of information to be represented simultaneously (Physical activity, Nutrition, Measurements)
3	The professional closes the application

Use Case 3 - The professional checks the glycaemic levels of the patient

Figure 127. Use Case 3: The professional checks information on glycaemic levels

4. Physician goal-setting configuration

Use Case nº	4
Title	The professional configures the goal-settings for the patient
Actor	Professional
Description	The professional sets or modifies goals to be achieved by the patient (based on an agreement with patient) in a certain period of time and following a certain process
Steps	
1	The professional uses sub-flows 4.2
2	The professional confirms the settings
Post-Condition	PO.1
Description	Settings are sent and confirmed by the patient in the PMD
Sub-Flow nº	4.1
Title	The professional sets goals for the patient
Description	The professional sets goals to be achieved by the patient (based on patient's evolution) in a certain period of time and following a certain process
1	The professional chooses the option to set goals for the patient

2	<p>The professional sets</p> <ul style="list-style-type: none"> - Goals - Timing - Process to be followed - Recommendations <p>Expected results</p>
Sub-Flow nº	4.2
Title	The professional modifies one or more goals to the patient
Description	The professional modifies the goals (it can depends on patient's goal evolution)
Steps	
1	The professional chooses the option to modify one or more goals for the patient
2	<p>The professional sets</p> <ul style="list-style-type: none"> - Goals - Timing - Process to be followed - Recommendations - Expected results
3	The professional confirms the settings
Post-Condition	PO.1
Description	Settings are sent and confirmed by patient in the PMD

Use Case 4 – The professional configures goal-setting for the patient

Figure 128. Use Case 4: The professional configures the goal

A.10 List of Educational Knowledge Topics

1. Dietetic Introduction
2. Dietetic category of dishes
3. Dietetic, meal composition
4. Treatments
5. Hypoglycaemia definition
6. Hypoglycaemia symptoms
7. Understanding of review importance
8. Annual review preparations
9. Diet Management
10. Hypoglycaemia, recommendations
11. Hyperglycaemia and complications, principles
12. Hyperglycaemia and complications, causes
13. Hyperglycaemia, introduction on complications
14. Insulin preparing and mixing
15. Diabetes and arteries
16. Compliances
17. Lifestyle
18. Disease Understanding
19. Physical Exercise Introduction
20. Physical Exercise Muscles
21. Physical Exercise and calories
22. Foot care guidelines
23. Diabetic food
24. Diabetes and travel
25. Pregnancy Managements in DMT1
26. Food intake for stranger or analphabetic
27. Diabetes management in travel
28. Education for patient performing sport
29. Management of complication
30. Educative session of foot care