



# **Procuring innovative ICT for patient empowerment and self-management for type 2 diabetes mellitus**

Napoli, 6 Giugno 2017

## **I requisiti tecnici dello strumento innovativo per la gestione e l'empowerment del paziente con diabete di tipo 2**

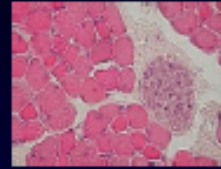
*Giovanni Annuzzi*

**UOC Diabetologia, AOU Federico II, Napoli**

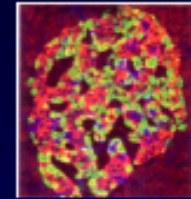
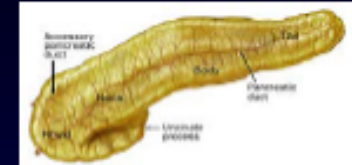
# Diabete mellito tipo 2



**Fegato**  
Aumentata  
produzione di  
glucosio

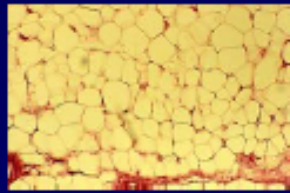


**Muscolo scheletrico**  
rRdotta utilizzazione di glucosio  
(trasporto, deposito, ossidazione)



**Pancreas endocrino**  
Ridotta secrezione insulinica  
Aumentata secrezione di glucagone

**Iperglicemia**



**Tessuto adiposo**  
Rilascio di molecole  
diabetogene



**Intestino**  
Ridotto effetto incretinico

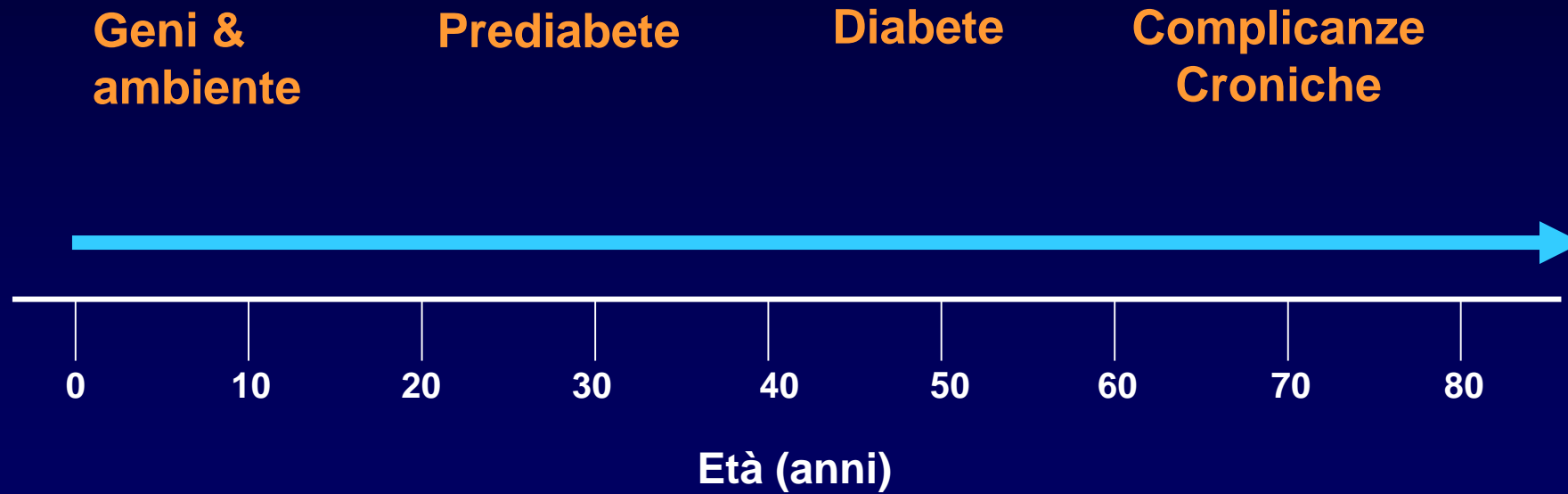


**Rene**  
Aumentato riassorbimento  
di glucosio

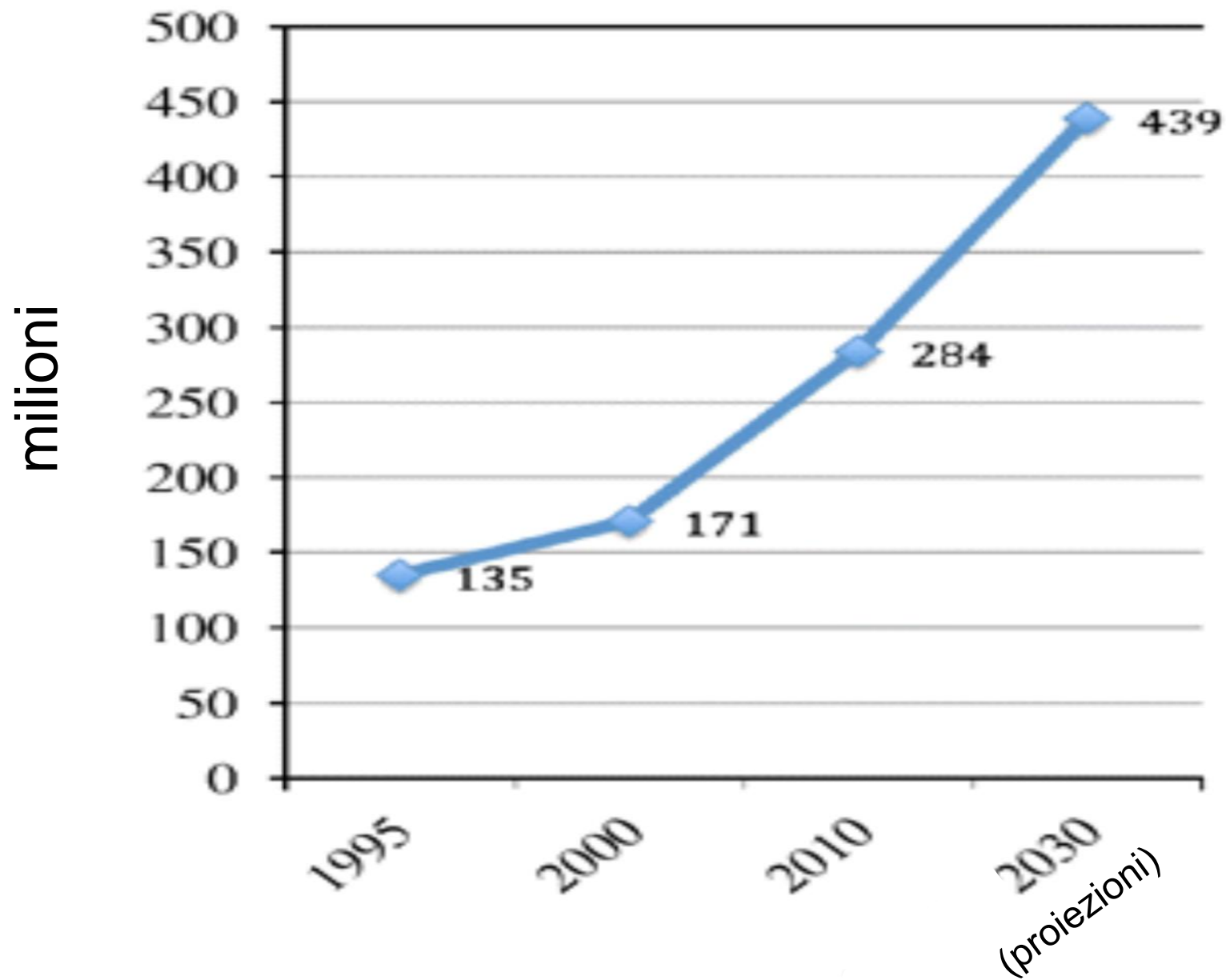


**Cervello**  
Alterato controllo metabolico

# Diabete tipo 2: una malattia cronica



# Numero di persone affette da Diabete mellito nel mondo



# Il diabete noto in Italia

Stima dall'Osservatorio ARNO Diabete CINECA-SID - 2014

Popolazione generale: ~61.000.000

Diabetici noti ~4.000.000

Tipo 2 ~3.500.000

Tipo 1 ~200.000

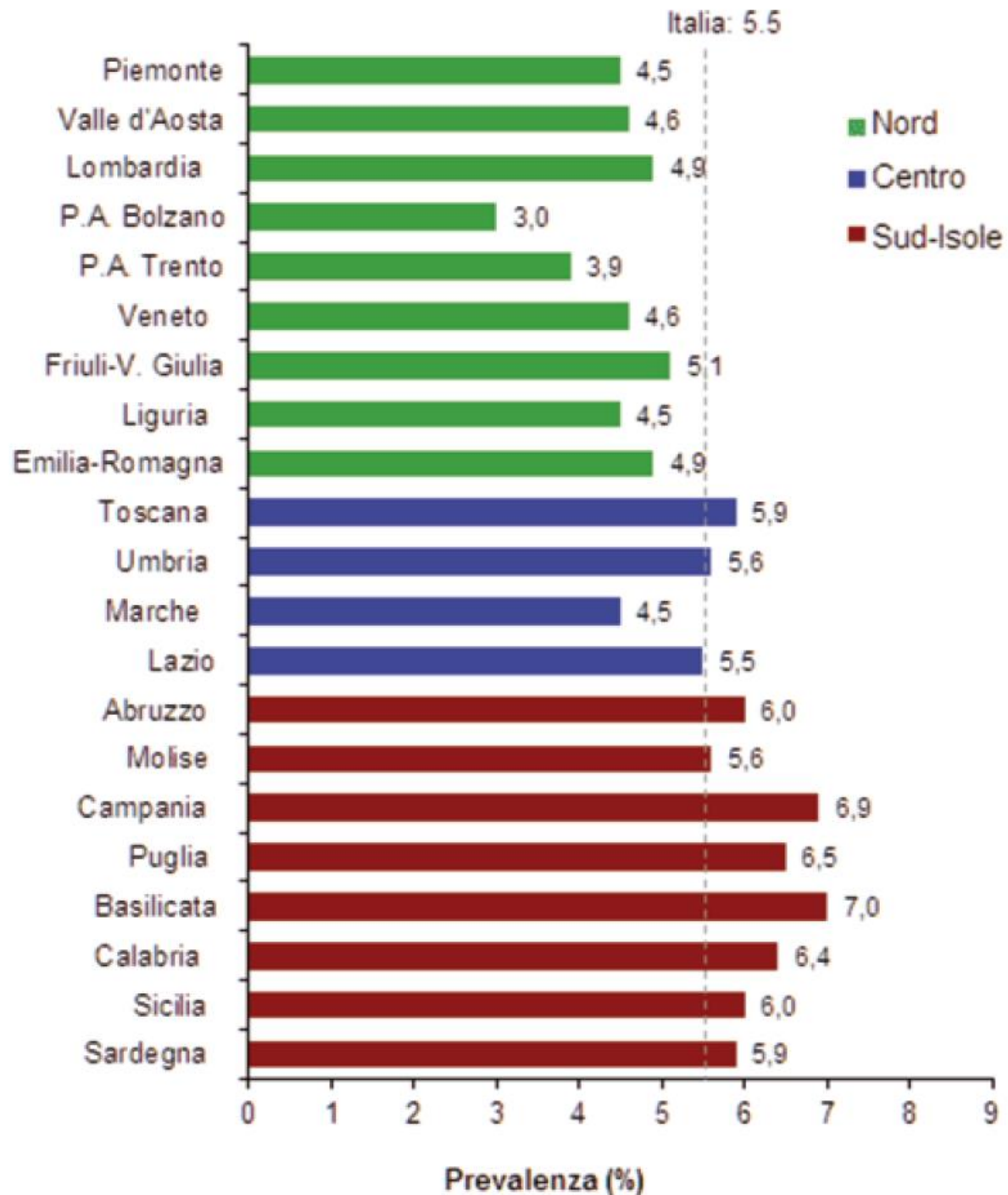
LADA ~200.000

Monogenico (MODY, ecc.) ~50.000

Secondario ~50.000



# Prevalenza del diabete in Italia in base alla distribuzione geografica (dati ISTAT 2014)

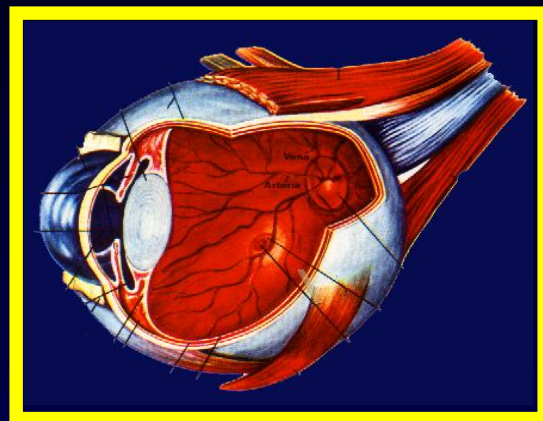


# Diabete e pre-diabete in Campania

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Diabete noto	~ 400.000
Diabete ignoto	~ 200.000
IFG e/o IGT	~ 300.000
<i>Totale</i>	~ 900.000

# Diabete: danno d'organo sistemico

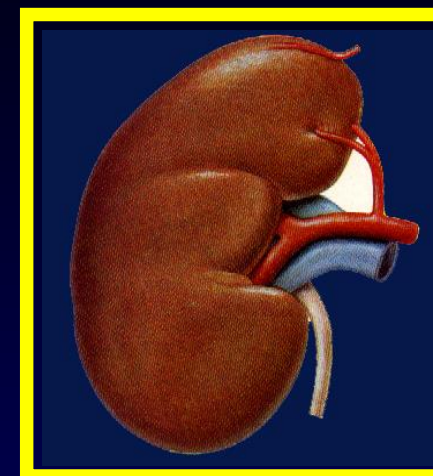


Occhio (retina)

Cute

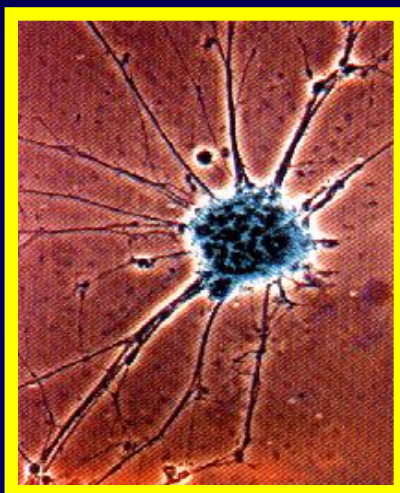
Gonadi

Apparato  
oste articolare



Rene

**Diabete**

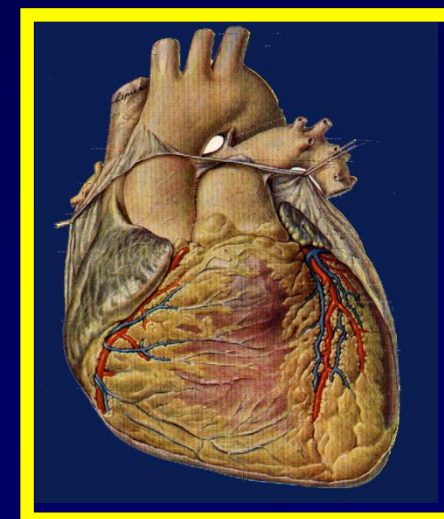


Nervi

Tubo  
digerente

Cervello

Sistema  
immune



Cuore & Vasi



# Diabete: complicanze gravissime e disabilitanti



**Prima causa  
di cecità**

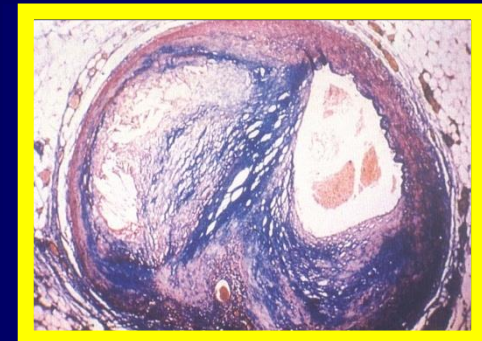


**Causa maggiore  
di insufficienza  
renale & dialisi**

**Diabete**



**Prima causa  
di amputazione  
non traumatica**



**Concausa  
nel 40-50% di  
infarti e ictus**

# Diabete: ridotta qualità di vita

## Azioni richieste ad un paziente diabetico nel corso della vita:

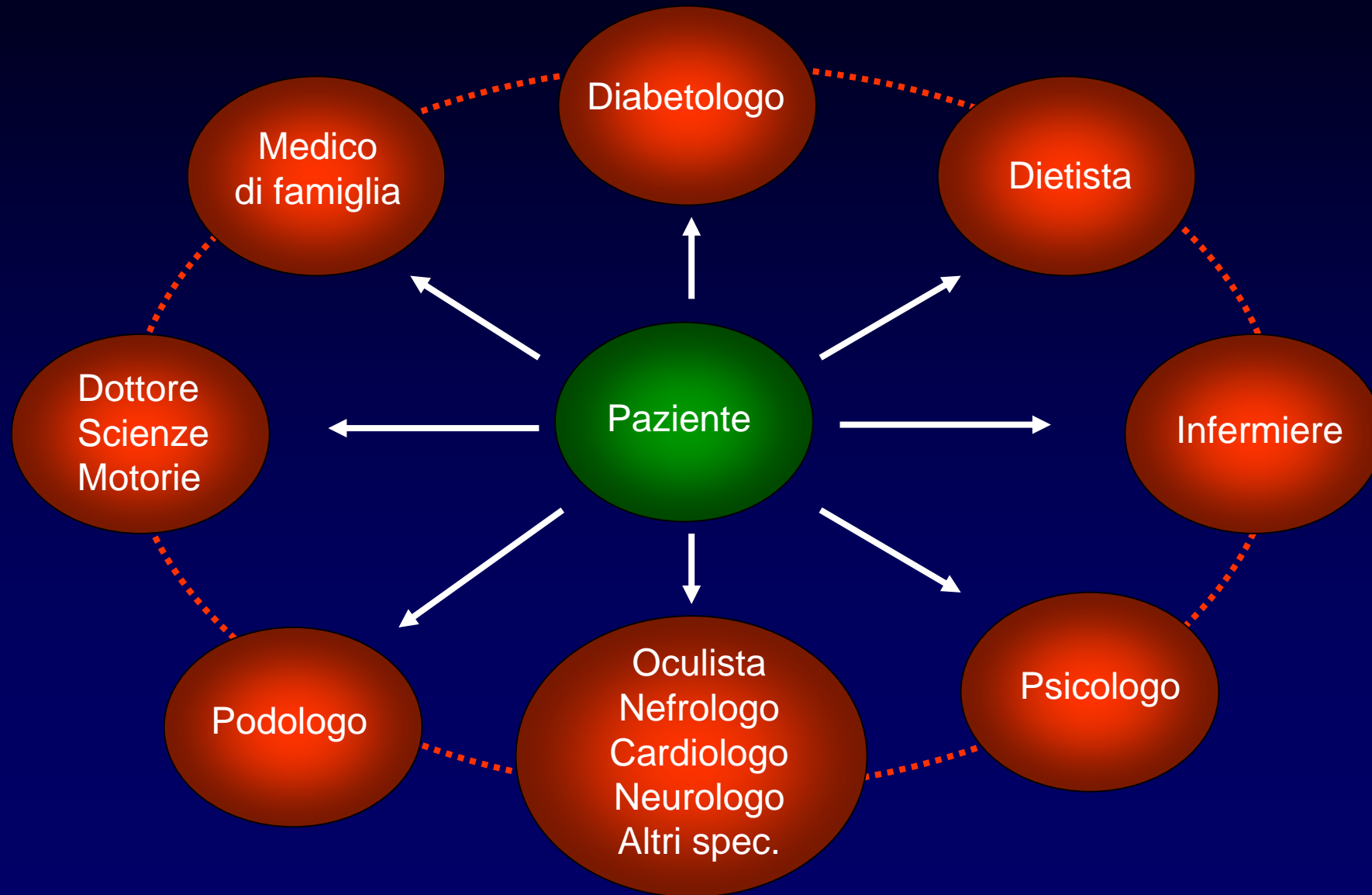
- Dieta (un minimo di 3 volte al giorno)
- Attività fisica (almeno una volta al giorno)
- Farmaci antidiabetici orali o iniettabili (1-4 volte al giorno)
- Altri farmaci (1-4 volte al giorno)
- Autocontrollo glicemico (variabile ma può essere 6 volte al giorno)
- Visite mediche per il controllo del diabete (un minimo di 2 all'anno)
- Visite mediche per le complicanze (numero variabile)
- Esami di laboratorio (un minimo di 2 volte all'anno)

**Nel corso della vita un paziente diabetico deve imporsi da 100.000 a 500.000 azioni che peggiorano la sua qualità di vita**

# Costi del Diabete in Italia

- Costi **diretti SSN** (cura della malattia e delle sue complicanze acute e croniche) = 16 miliardi € per anno
- Costi **diretti personali** (spesa personale non coperta dal SSN) = 3 miliardi € per anno
- Costi **indiretti tangibili personali, sociali** (assenza dal lavoro, mancato guadagno, impegno dei familiari, ecc.) = 12 miliardi € per anno
- Costi **indiretti intangibili o morali** (disabilità, ridotta qualità e aspettativa di vita)

# Diabete: una patologia tanto complessa da richiedere l'impegno di molti professionisti



**Primo livello**

**MMG**

**Secondo livello**

**Centro Diabetologico**

**Terzo livello**

**Centro per la Cura del  
Piede diabetico**

**Ispezione  
Piede**

Lesione  
piede  
o dismorfia

Assenza di  
lesione o  
dismorfia

Istruzione  
(decalogo)  
Controllo  
periodico  
*ogni 6-12 mesi*

Screening piede  
a rischio  
Monofilamento  
Biotesiometria  
ABI  
Rinforzo istruzione  
*Ogni 2-3 anni*

Rischio  
basso

Rischio  
alto

Medicazioni  
Semplici-Avanzate

Team multidisciplinare\*  
Inquadramento  
Diagnostico  
Tampone-Biopsia  
Rx-Ecografia  
RMN-TAC  
Ecodoppler AAll  
Angiografia

Chirurgia  
minore  
+/- PTA

Chirurgia  
maggiore  
+/- PTA

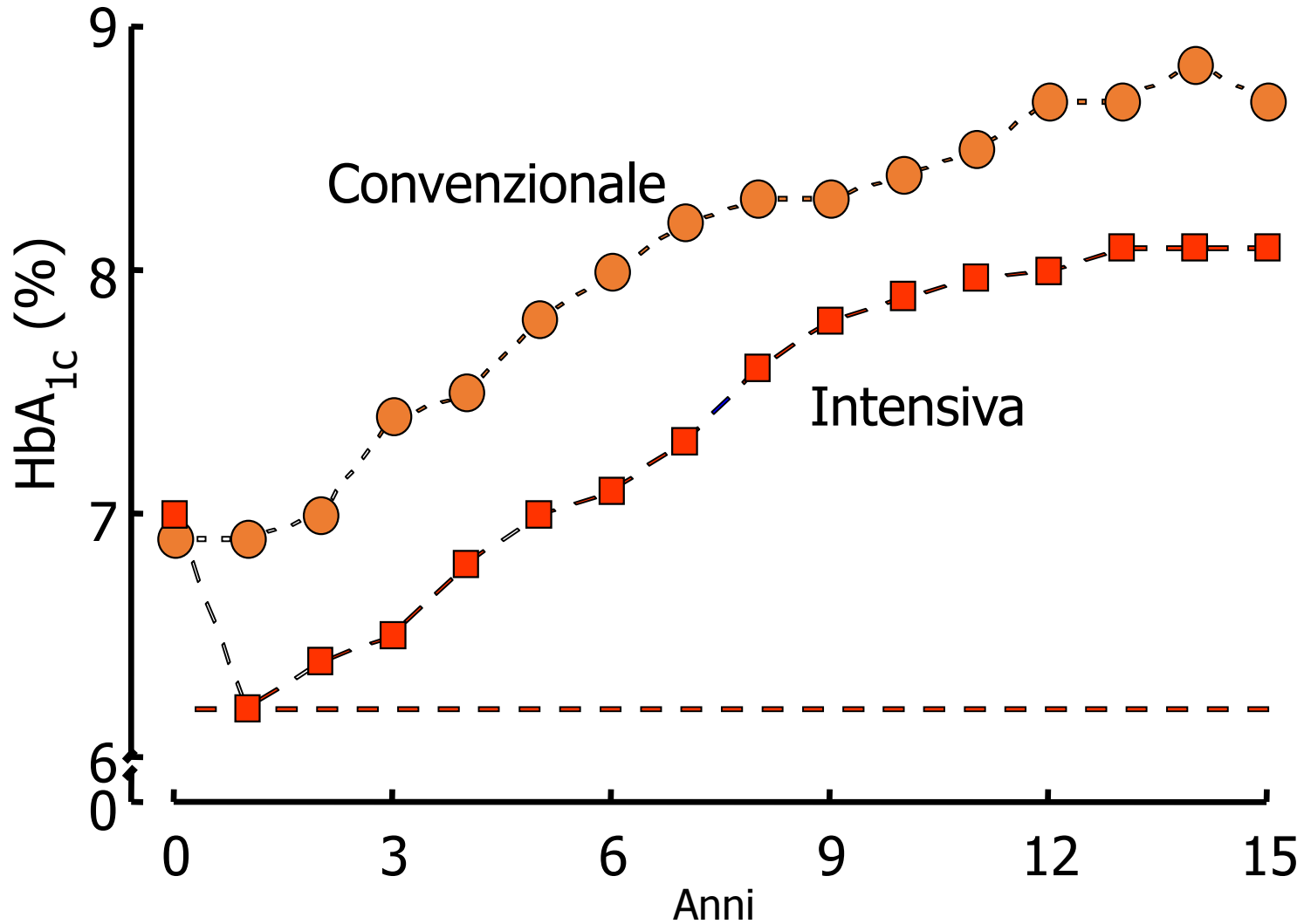
Medicazioni  
Semplici-Avanzate

**Team multidisciplinare:** diabetologo, infermiere esperto, podologo, radiologo, ortopedico, chirurgo plastico, chirurgo vascolare, infettivologo, fisiatra, tecnico ortopedico

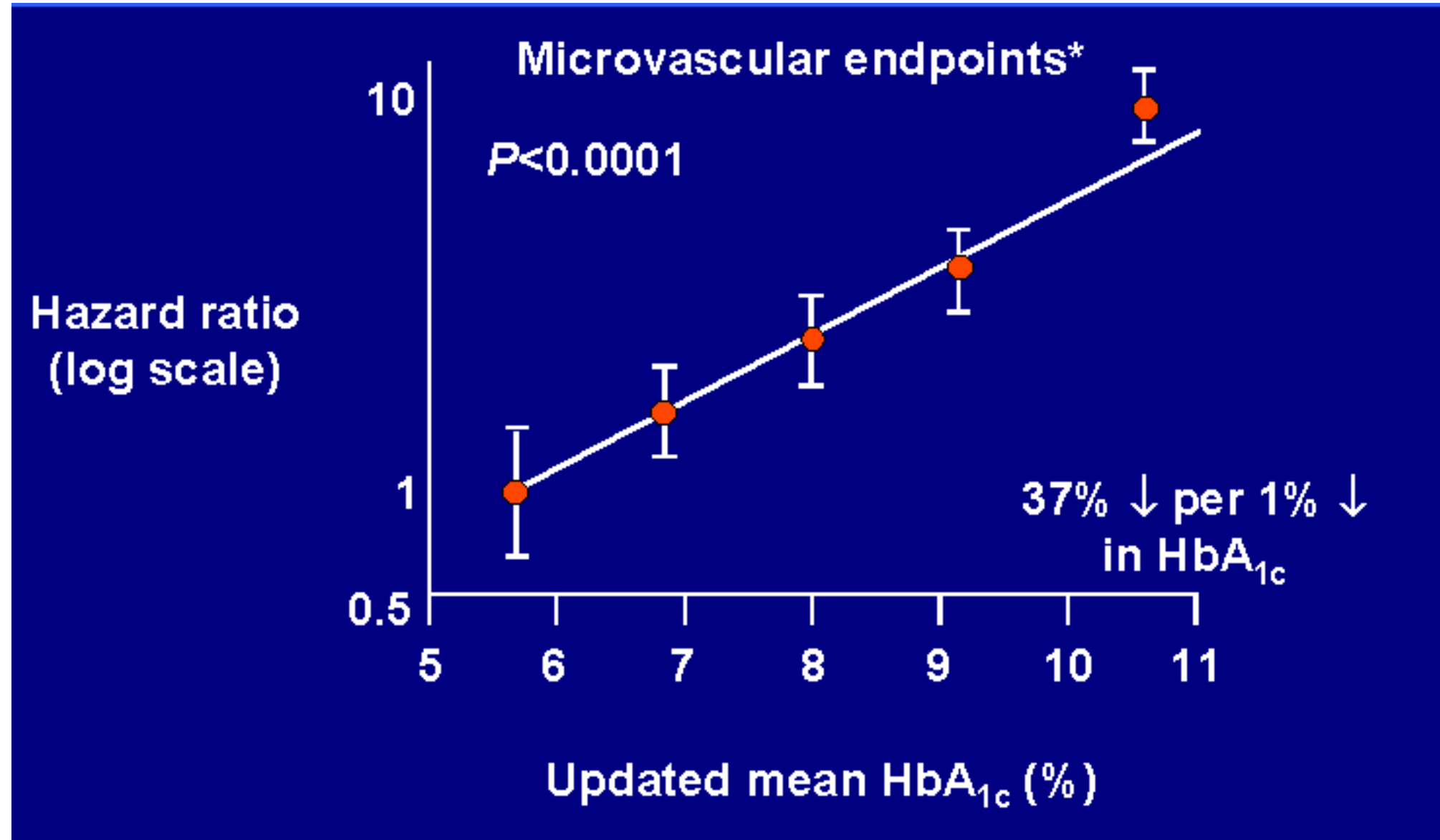
# UKPDS (United Kingdom Prospective Diabetes Study )

SCOPO: valutare l'efficacia del compenso glicemico  
nel prevenire/ritardare la comparsa delle  
complicanze micro- e macrovascolari in pazienti con  
Diabete mellito tipo 2

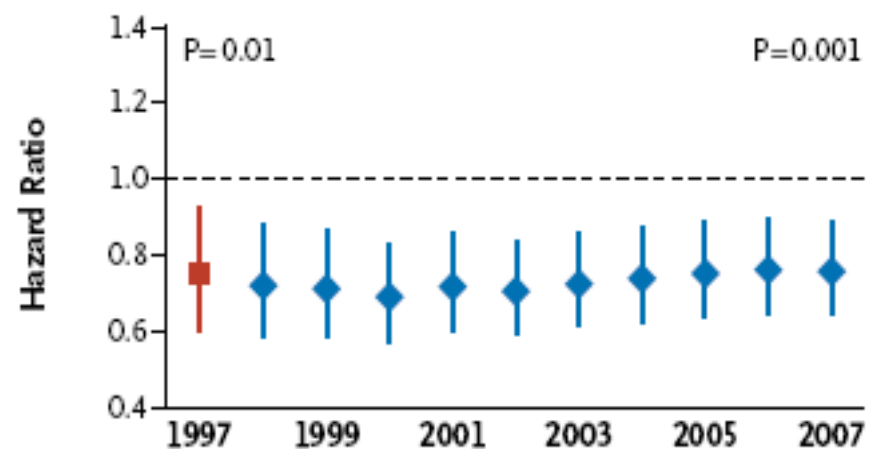
# UKPDS: HbA<sub>1c</sub> nei gruppi in terapia convenzionale e intensiva



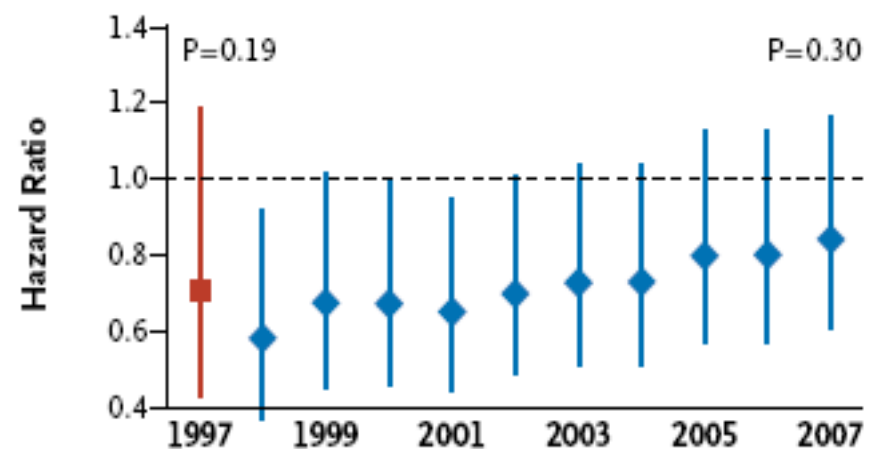
# UKPDS: Effetti del controllo glicemico sulle complicanze microvascolari



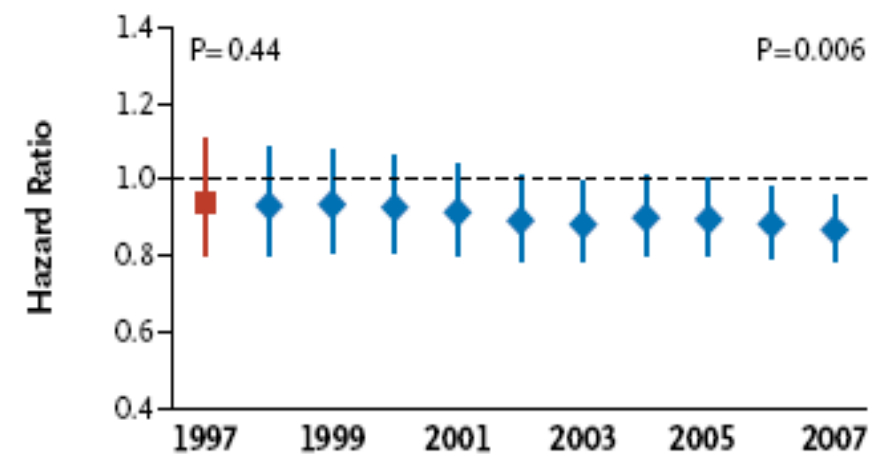


**E Microvascular Disease****No. of Events**

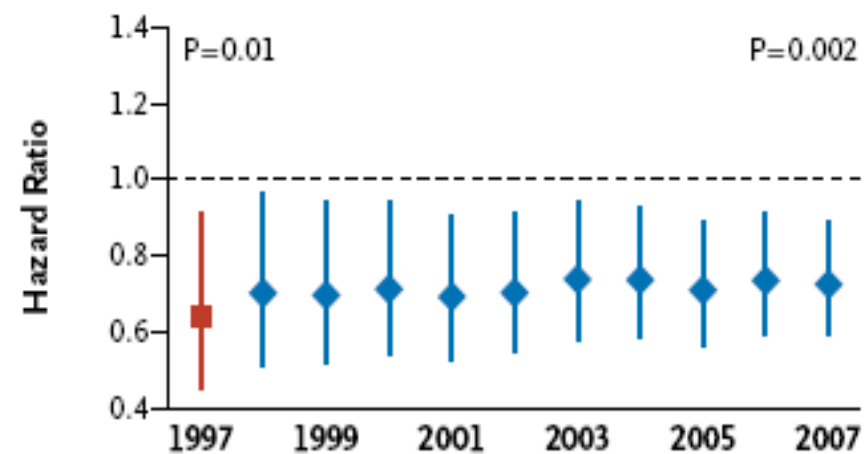
Conventional therapy	121	155	187	205	212	222
Sulfonylurea-insulin	225	277	338	378	406	429

**F Microvascular Disease****No. of Events**

Conventional therapy	38	58	70	73	74	78
Metformin	24	37	44	52	58	66

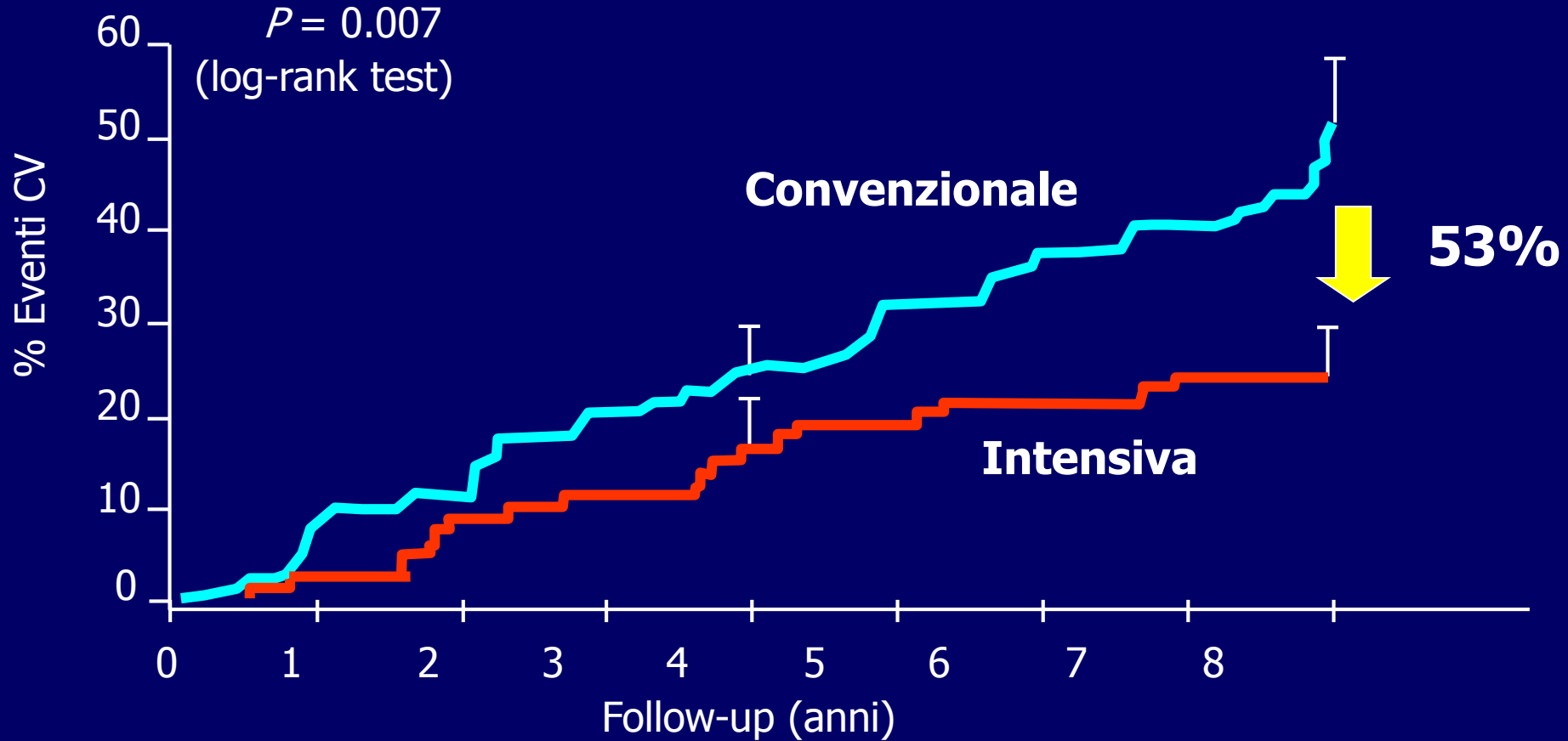
**G Death from Any Cause****No. of Events**

Conventional therapy	213	267	330	400	460	537
Sulfonylurea-insulin	489	610	737	868	1028	1163

**H Death from Any Cause****No. of Events**

Conventional therapy	89	113	136	160	183	217
Metformin	50	70	86	110	123	152

# Effetti dell'intervento multifattoriale sugli eventi cardiovascolari (Studio Steno-2)



# Strumenti nella terapia del diabete

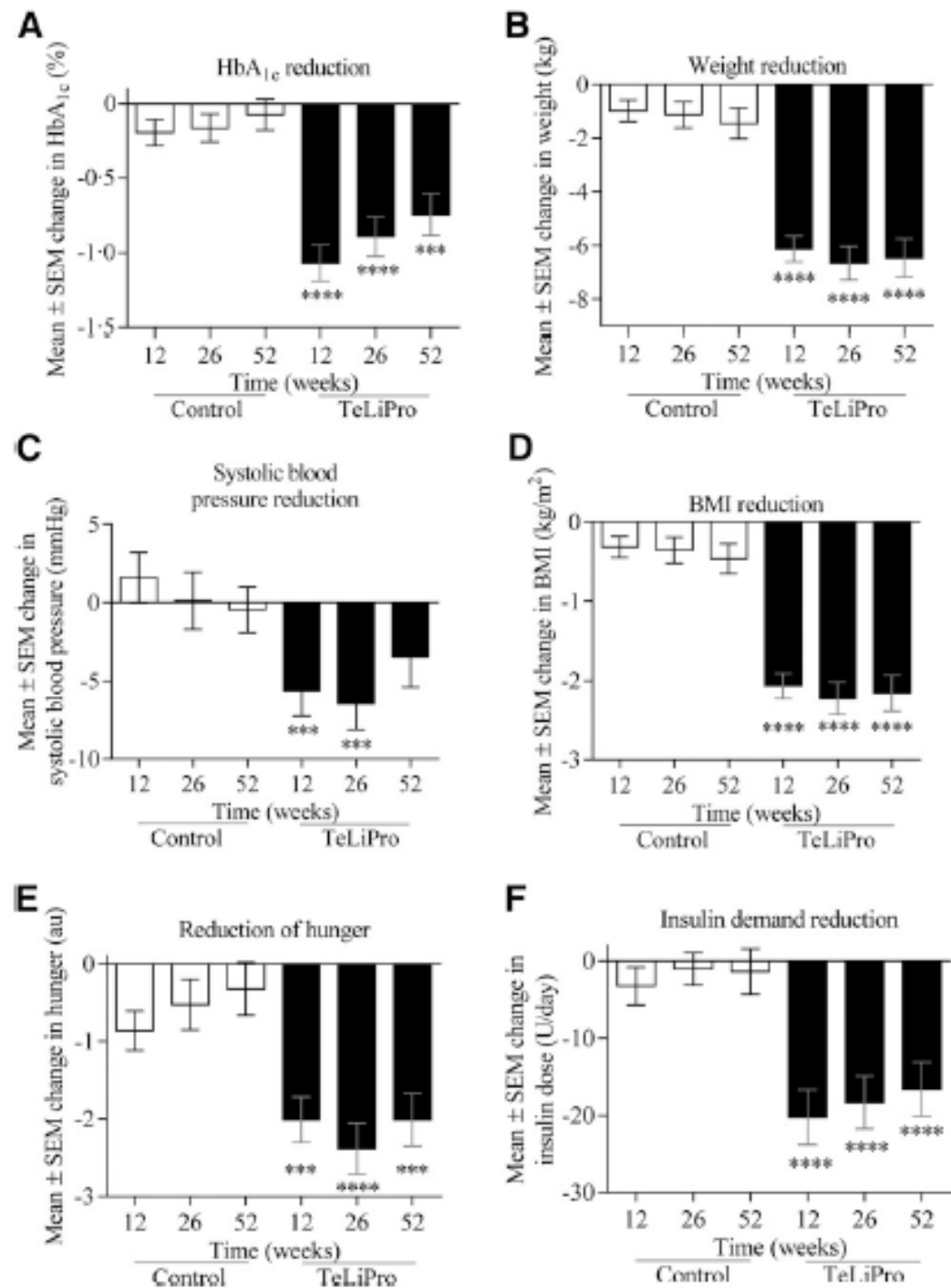
- Partecipazione del paziente
- Alimentazione corretta
- Attività fisica regolare
- Automonitoraggio glicemico domiciliare
- Anti-diabetici non insulinici (orali e iniettabili)
- Insulina (eventualmente con microinfusore)
- Farmaci per altri fattori di rischio

# Efficacy of the Telemedical Lifestyle intervention Program TeLiPro in Advanced Stages of Type 2 Diabetes: A Randomized Controlled Trial

<https://doi.org/10.2337/dc17-0303>

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Matthias Fuchs,<sup>3</sup> Michael Schneider,<sup>4,5</sup>  
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Stephan Martin<sup>1,6</sup>

Diabetes Care 2017





# ProEmpower

The procurers of ProEmpower are in search for an **innovative** solution which will not only lower the **expenses** relating to diabetes detection and treatment, but also will improve the **quality of life** of diabetic patients by **empowering** them with a self-management program.

The program should aim to **encourage** the patients and improve their **ability to make informed decisions** on managing their own health, as well as improving their **self-esteem** and **responsibility** for their own health.



Sono in corso di definizione i requisiti  
per lo sviluppo dello strumento  
ProEmpower

# Interoperability

- The ProEmpower solution shall be **hosted on servers** physically located within the geographic regions of the four pilots.
- The ProEmpower solution shall be able to **exchange information** (read and write data) with the systems of the four procurers (Turkish, Spanish, Portuguese, Italian). These include EHR and PHR systems.
- The ProEmpower solution shall support visualisation using the following
  - browsers: Chrome48 & above, FireFox40 & above, IE10 &above, Opera35 & above, Safari10 & above
  - mobile app platforms: Android, iOS, Windows Phone

## **Millewin**

Software for the management of General Practitioners activities. Structured and updated by GPs, allows collecting comments, tips, suggestions.

## **MyStar Connect**

Diabetes data management software platform that supports healthcare professionals in delivering outpatient care in Diabetes Centers.

## **AirDiabete**

Web service for transmission to Campania Region of periodic reports assessing the participation of the GPs to the integrated management of the diabetic patients.



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## Diabetes Shared Care Plan

**A shared electronic document between the patient and the health professionals**

The Shared Care Plan shall allow for

- **editing and updating** the various contents, such as issues, goals, patient information, medication and doses, alerts, etc.
- **integrating** any new information or **changing** existing information recorded in the plan in the respective EHR (and PHR if applicable) system of the procurers.
- **sharing** contents with other professionals and with members of the patient's family. The sharable data for the two groups (healthcare professionals, family) shall be defined.

## The Shared Care Plan shall

- be accessed by patients and healthcare professionals using **secure authentication methods** in accordance with the existing methods of the four procurers. The security and authentication approach shall be in conformance with relevant privacy and security policies and laws applicable to the four procurers.
- allow for performing meaningful **queries** with the data, e.g. all values of a measured parameter in the last six months.
- use **appropriate formats** for the different input items, e.g. dropdown menus, text fields, checkboxes, etc.
- **generate reports** using data and visuals for different aspects, e.g. goals, alerts, medication, queries. The reports shall be available in different formats (minimum: PDF, HTML) and print-friendly.

## The Shared Care Plan shall

- include **different topics** structured in a **comprehensive** manner (e.g. sections, tabs, sheets). Minimum topics to be addressed are: patient information, goals setting and tracking, recording of issues, medication and doses, scheduling alerts and responding to them, reports and visualisation.
- allow for **setting goals** for the patient regarding i) diabetes-related measurements (e.g. blood glucose level, glycated haemoglobin), ii) diet and nutrition (e.g. weight, carbohydrate intake, body fat), iii) exercise and fitness, and iv) other (e.g. stress levels).
- allow for sending out notifications and alerting of deviations to the professionals and/or patients when predefined value ranges of measurable parameters are overstepped. Alerts and notifications can be in the form of short (suitable for mobile devices) and longer (e.g. as part of the SCP platform) text.

1. During a session (visit, control check) patient and physician discuss **different goals** (e.g. physical activity, nutrition, blood glucose, weight, other physiological parameters).
3. System displays appropriate mask and **units** (e.g. for weight goals: target in kg, timeframe for target achievement, for sleep: target in hours per day, etc.).
4. Physician and patient can **update** the goals during sessions. Physician enters the agreed goals.
5. Physician (at all times) and patient (when allowed) can **access** the recorded goals and track progress.
6. System analyses incoming data (e.g. food entries, physical activity entries, updates in the SCP, etc.) and **generates reports**. **Alerts** communicate deviation from goals, or unmet goals for the specified period.

## The Shared Care Plan shall

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1. System monitors various data from the other use cases. For example: training modules, nutrition, physical activity, body mass index, depression, blood glucose.
2. System issues alerts to the patient and the physician when there are deviations from pre-set information, e.g. agreed goals, monitored parameters.
3. The system sends notifications **to the patient** (personalised information, tips and advice about nutrition, physical activity, community engagement, and training, scheduled events, community news, and **the physician** (scheduled events, check-ups).

The Shared Care Plan shall allow for scheduling different events relevant for patients and professionals. The ProEmpower solution shall assist them with keeping track of the events and ensuring that they are realised.

1. During a visit, patient and physician enter different events for the foreseeable future (e.g. they plan together until their next meeting, which itself is planned and put into the schedule). For each new event entry, at least the following information is recorded:
  - Name of event, due date and time, notes related to the event
  - Occurrence (one-time vs. recurring) and frequency (e.g. every three months)
  - Notification target (e.g. just for patient, for physician, for both)
  - Event reminders (e.g. sending an alert 1, 3 days before event, 30 minutes before event, etc.)
3. System manages all events and sends reminders according to the entries.
4. Physician and patient can access the scheduled events at all times. Patient can enter own events (e.g. when at home); in these cases the only notification target can be the patient.



# Patient Decision Support

The ProEmpower solution shall be able to

- **deliver messages to the patient.** Messages can come directly from the physician, or can be based on data analysis (e.g. notification in cases of deviation from goals, appropriate tips for better management, etc.).
- **deliver messages initiated by the patient to the physician** (e.g. when the patient is experiencing side effects). Only specific situations should be communicated in this way, as the physician is not expected to respond in real time. In cases when is out of office and/or the patient message indicates an emergency situations (e.g. severe hypoglycemia and shock) triage to a call centre or 112 service.

- The ProEmpower solution shall enable **assessment of the nutrition** of the patient based on food intake and dietary composition. The assessment outcome shall be in the form of reports (e.g. for a 24h dietary record).
- The ProEmpower solution shall enable **assessment of the physical activity** of the patient based on recorded exercise regimen captured by the ProEmpower solution. The assessment outcome shall be in the form of reports as well as personalised messages (e.g. tips, recommendations).

# Training patients

The ProEmpower solution shall support training of patients

- during **physical meetings** and as **offline** follow up (e.g. when the patient is at home)
- by **healthcare professionals**: diabetologists, nurses, dieticians, GPs.
- **personalising** according to: age, sex, working condition (non-active/office work, mobile/out-of-office work, housewife, shift work, etc.), numbers (individual and group sessions), according to diagnosis (early stage, advanced, etc), prescribed drugs (oral, insulin, etc.), temporary weight gain observed).
- on different **topics**: General diabetes knowledge, Tobacco and Alcohol, Diet and Nutrition, Physical activity and exercise, Hygiene (mouth, feet), Attitude to Intercurrent Diseases, Hyper- and hypoglycaemia, Blood glucose self-control, Insulin therapy, Drug therapy, Diabetes complications, Life with diabetes, Sleep and stress.

1. Patient follows the instructions of the physician and moves to the part of the healthcare facility where a nurse can take over.
2. Nurse retrieves from the system patient data and more specifically, the level of disease (ICD codes are used) in order to determine which modules / topics should be covered in the training.
3. Nurse administers diabetes training to the patient through verbal explanations. The training may also include demonstrations (e.g. how to use medical devices).
4. Nurse provides brochures, notes, etc. to the patient.
5. Nurse finalises the training and marks the event in the EHR system. Normally no further sessions are scheduled.

1. Patient records parameters related to food intake using manual entries (e.g. "apple"), barcode scans and/or photo uploads.
2. Upon patient entries, system
  - analyses total energy intake, body weight, body weight changes, energy balance, dietary composition
  - checks ingredients against active agents of diabetes drugs taken by the patient
  - gives suggestions for balancing the meal based on current entries and on past meals
  - provides healthy eating lessons/tips after each meal
  - provides recipes based on food preferences
3. Continuously, the system gives out warnings to the patient (e.g. too much carbohydrates in two days, or drug interaction warnings)
4. Professionals can monitor entries periodically and provide feedback to the patient, setting and adjusting target intake goals for the different times of the day and for different periods, which are flagged as such and accompanied by notes and explanations, and are reported by the system to the patient.

1. Patient records parameters related to physical activity. Some may be **recorded automatically**, e.g. when using wearable devices (smart bands like Fitbit, Garmin, Polar, Samsung... by Apple, Android, etc.), including: Activity (type, duration, distance, intensity, steps, floors), Sleep (quality, duration), Goals entries (e.g. weight, activity targets), Schedules, Heart rate, Calories burned, Blood glucose levels.
2. Upon patient entries, the system
  - proposes duration and intensity of selected physical activity
  - gives advice related to nutrition (e.g. foods or drinks to take or not, before and after exercise and quantity based on the training duration and intensity).
  - gives suggestions, reminders & alerts for exercise routine or walk routine
  - provides physical activity lessons / tips for the everyday routine
  - continuously, provides positive feedback to the patient and tracks goals. The system gives out warnings to the patient (e.g. poor activity daily, or physical condition alert, excess of sedentary).

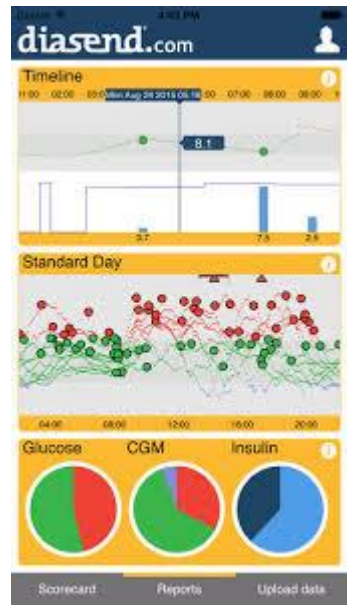


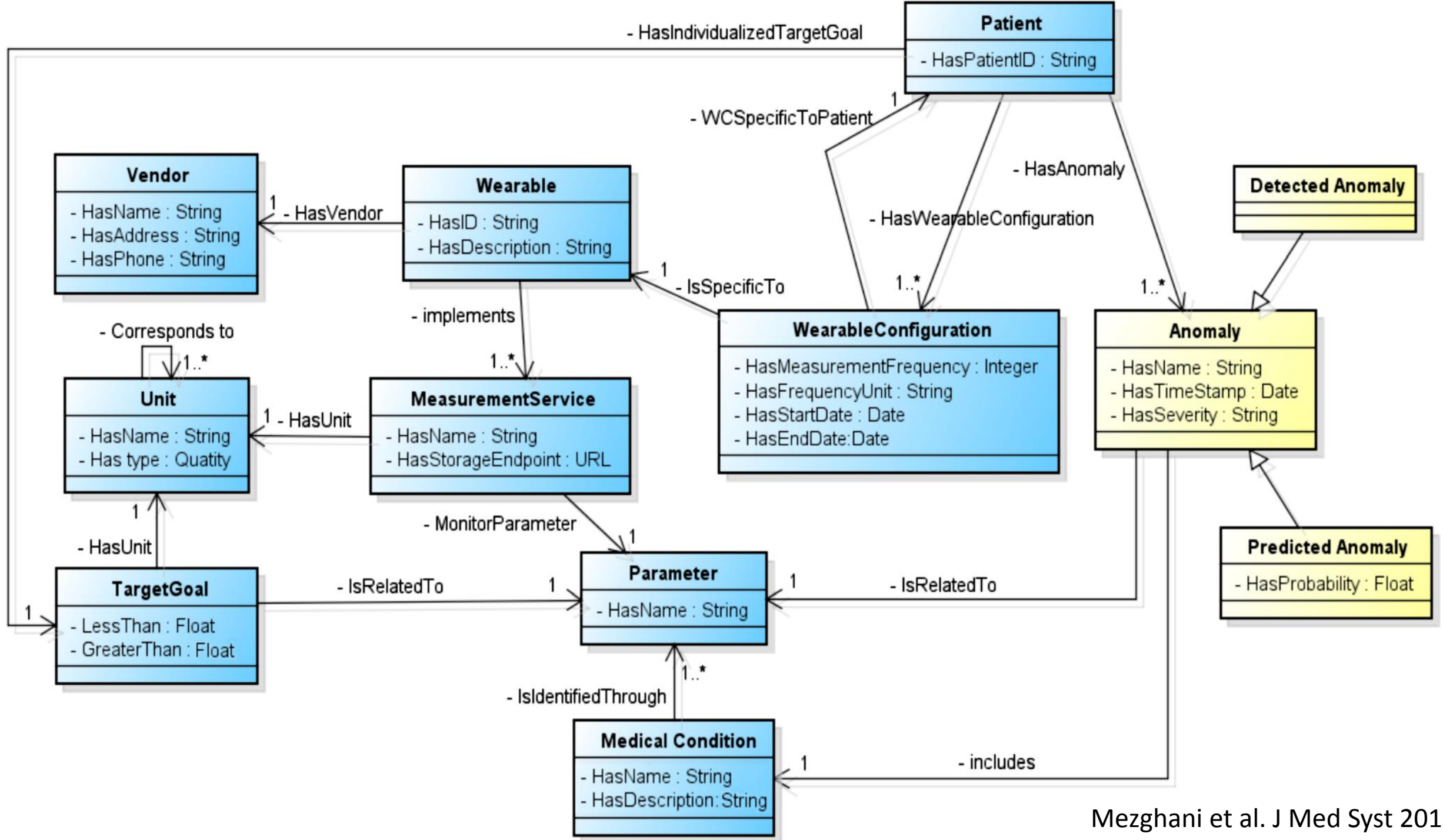
Mobile apps

CareLink<sub>USB</sub>



CareLink<sub>USB</sub>







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  - gives suggestions, reminders & alerts for exercise routine or walk routine
  - provides physical activity lessons / tips for the everyday routine
  - continuously, provides positive feedback to the patient and tracks goals. The system gives out warnings to the patient (e.g. poor activity daily, or physical condition alert, excess of sedentary).

3. Physician and/or nurse can **monitor** entries periodically (weekly or monthly) or view summary reports and provide feedback to the patient. Physician can set and adjust target goals for the different activities and for different periods, which are flagged as such and accompanied by notes and explanations, and are reported by the system to the patient. He can share physical activity data with mentor or trainer or someone in the community or the personal monitors.

