



VI CONVEGNO NAZIONALE
CENTRO STUDI E RICERCHE - FONDAZIONE AMD

NAPOLI, 18-20 OTTOBRE 2012



CENTRO CONGRESSI
STAZIONE MARITTIMA



Nuove tecnologie per la gestione del diabete e loro utilizzo in gravidanza

D.Mannino

UOC Diabetologia Endocrinologia

A.O. BMM Reggio Calabria



A simple computer program for insulin dose adjustment
in diabetic patients.

Bellomo G, Santucci S, Mannino D, Alessi R.

**Comput Methods Programs Biomed. 1988 May-Jun;
26(3):257-8**

Telemedicine in the treatment of diabetic pregnancy.

**di Biase N, Napoli A, Sabbatini A, Borrello E, Buongiorno
AM, Fallucca F.**

Ann Ist Super Sanita. 1997;33(3):347-51.



Diabete e gravidanza

Diabete pregravidico

- Tutte le donne con diabete in età fertile **devono essere informate**
- Le donne con diabete in gravidanza devono praticare **l'autocontrollo domiciliare**
- Il **monitoraggio continuo del glucosio sc** può essere utile in gravidanza.....
- Le donne con diabete pre-gestazionale tipo 1 devono essere trattate con plurime somministrazioni di insulina sc, con schemi basal-bolus, o con l'utilizzo **del microinfusore (CSII)**.

Diabete gestazionale

- L'autocontrollo glicemico deve essere iniziato immediatamente dopo la diagnosi
- Nelle donne con diabete gestazionale la terapia insulinica deve essere iniziata prontamente se gli obiettivi glicemici non sono raggiunti entro 2 settimane di trattamento con sola dieta.



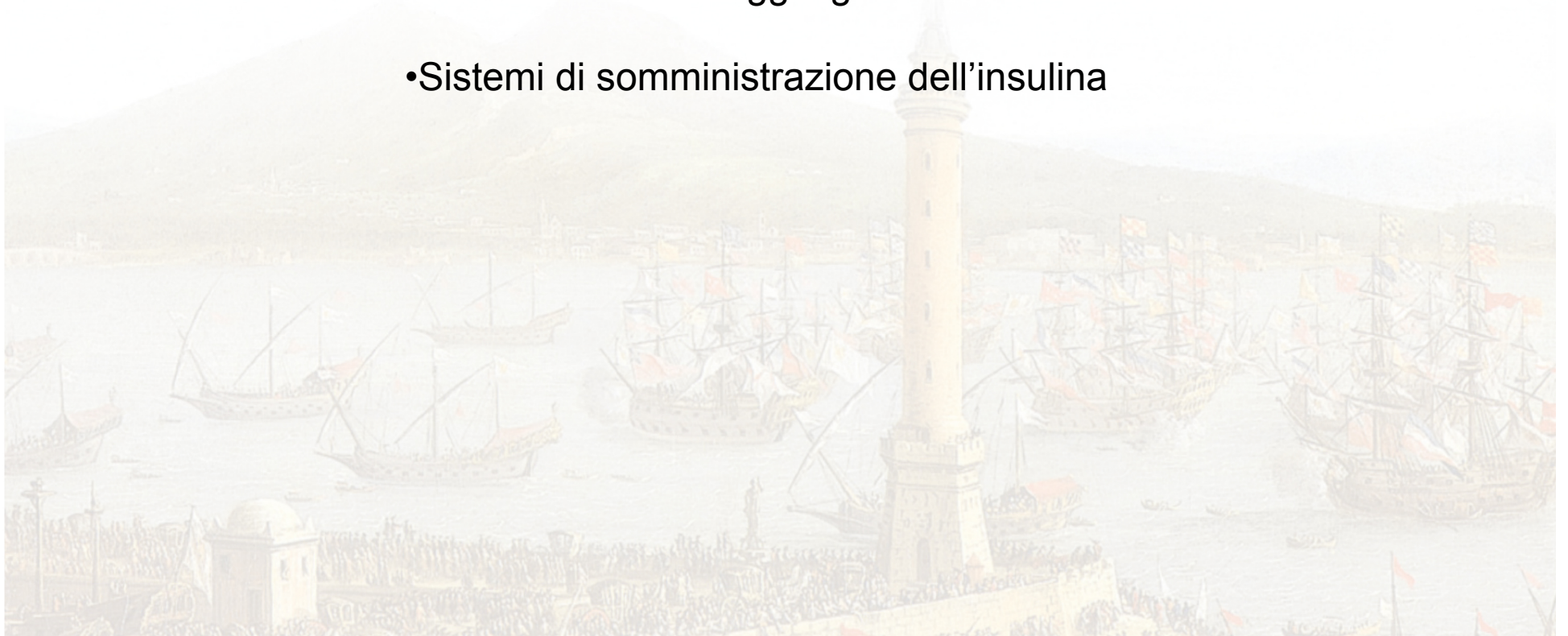
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- Programmi di educazione
- Sistemi di monitoraggio glicemico
- Sistemi di somministrazione dell'insulina





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Glucose Monitoring

First Glucose Meter





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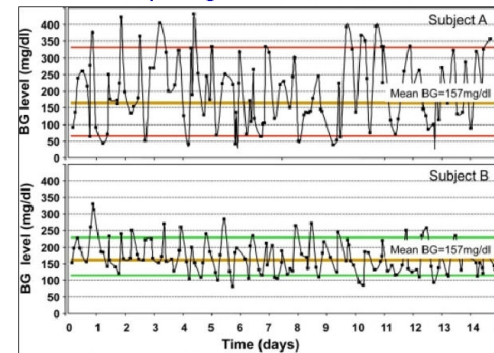
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TRIMELLITO EXPERIENCE					
DATE	WAZON	GLUCOSIA	WAZON	DOZ	WAZON AFFORD
10/10/12	0255	100	15	10	0255
10/10/12	0650	166	15	10	0255
10/10/12	0830	753			0255
10/10/12	0817	151			0255
10/10/12	0911	374	1		0255
10/10/12	1016	313			0255
10/10/12	1110	271			0255
10/10/12	1157	100			0255
10/10/12	1121	137			0255
10/10/12	1134	177			0255
10/10/12	1157	178			0255
10/10/12	1216	161			0255
10/10/12	1402	172			0255
10/10/12	1520	65	20		0255
10/10/12	1545	115	5		0255
10/10/12	1635	234			0255
10/10/12	1700	152	10		0255
10/10/12	1733	131	5		0255
10/10/12	1825	170			0255
10/10/12	1844	85	20		0255
10/10/12	1920	213			0255
10/10/12	2004	166			0255

Biagio Roadbook @ Ironman

Due profili glicemici a confronto...



Kovatchev, BP. Is Glycemic Variability Important in Assessing Antidiabetic Therapies. Current Diabetes Reports 2004, 4: 350-356



Time	Glucose	Insulin	...
07:00	100	0.5	...
08:00	120	0.8	...
09:00	140	1.2	...
10:00	160	1.5	...
11:00	180	2.0	...
12:00	200	2.5	...
13:00	180	2.0	...
14:00	160	1.5	...
15:00	140	1.0	...
16:00	120	0.8	...
17:00	100	0.5	...
18:00	80	0.2	...
19:00	100	0.5	...
20:00	120	0.8	...
21:00	140	1.2	...
22:00	160	1.5	...
23:00	180	2.0	...
00:00	160	1.5	...
01:00	140	1.0	...
02:00	120	0.8	...
03:00	100	0.5	...
04:00	80	0.2	...
05:00	100	0.5	...
06:00	120	0.8	...



La gestione dei profili è una strategia raccomandata ed approvata per ottimizzare il controllo glicemico¹

Oggi la ricerca dei profili può risultare difficoltosa e non fornisce un riscontro immediato: il diario non basta!

La maggior parte dei pazienti reagisce trattando subito il singolo valore glicemico fuori controllo e non ricerca eventuali profili glicemici²

76%



Pochi pazienti controllano precedenti valori glicemici alti e bassi per verificare se i propri valori glicemici sono parte di un profilo glicemico nascosto²

10%



Il 13% dei pazienti in terapia insulinica scarica i dati glicemici del proprio strumento a casa²

1 Pearson J. Bergenstal R. Diabetes Spectrum Vol. 14 No 2. 2001

2. People with Diabetes in the United States - A&U Study 2011. TNS.



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CGMS

Continuous Glucose Monitoring System



Injectable Glucose Sensor
SENCELL
Continuous Sensing Inside

- Micro sensor for injection under the skin
- Wireless, real time data transferring
- Based on osmotic pressure readings
- Data displayed on your wrist watch

*Inject and forget
Be watched and warned*

Photo of actual prototype
in development



LifeCare (Bergen, Norway)





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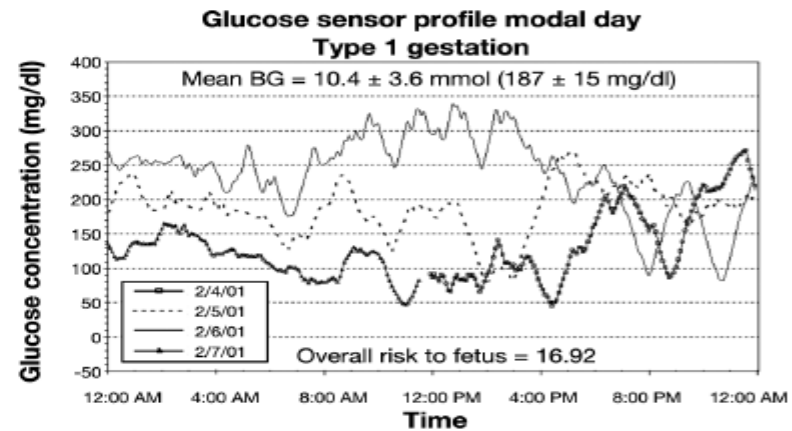
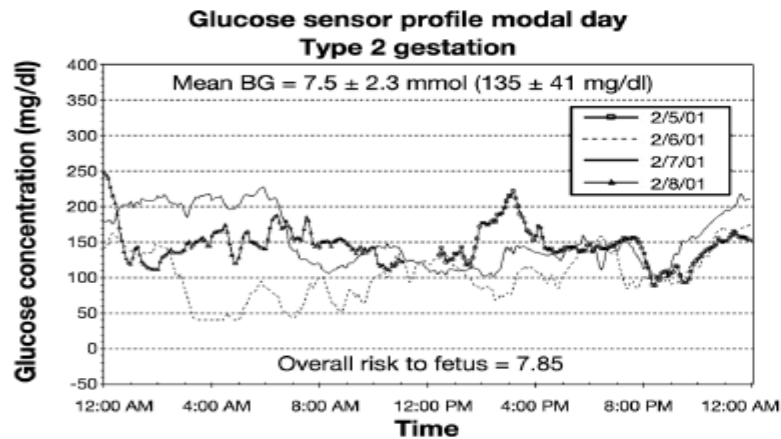
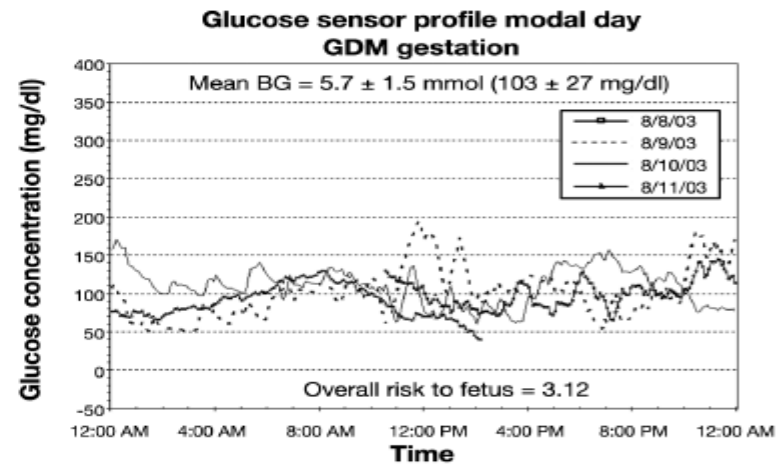
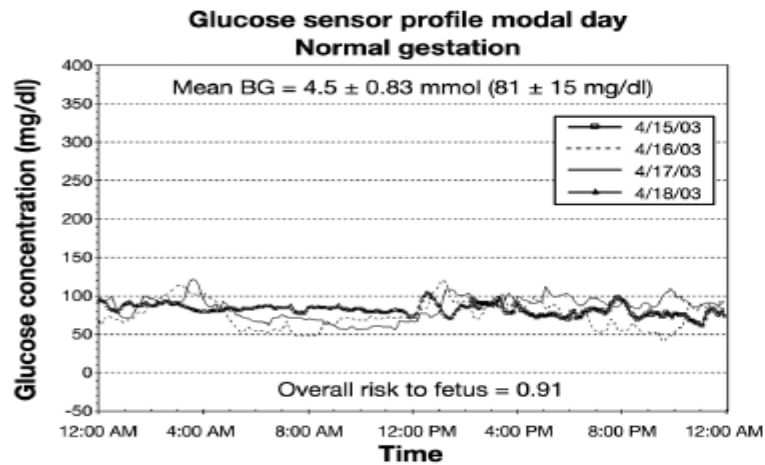


Journal of Diabetes Science and Technology
Volume 4, Issue 6, November 2010
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ORIGINAL ARTICLES

Fetal Risk Assessment in Pregnancies Complicated by Diabetes Mellitus

Howard C. Zisser, M.D.,¹ Michael A. Biersmith, B.S.,¹ Lois B. Jovanovič, M.D.,¹ Yariv Yogev, M.D.,² Moshe Hod, M.D.,² and Boris P. Kovatchev, Ph.D.³





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Insulin Delivery Modes





Insulin Delivery Modes

Insulin Pumps



- provide continuous insulin delivery
- infusion site needs to be changed only every 2-3 days





iOS



Android
Via Bluetooth Adapter





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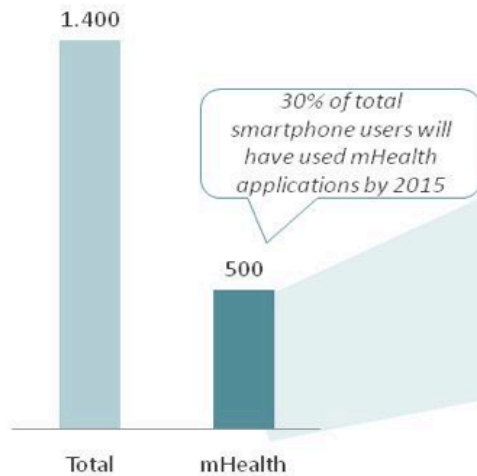
The [iLickit iPhone App](#) makes me question the progress of humanity. This app wants you to achieve size zero as it encourages you to lick the screen whenever it flashes a sumptuous meal. Not my idea of dieting. Price - \$1.99.



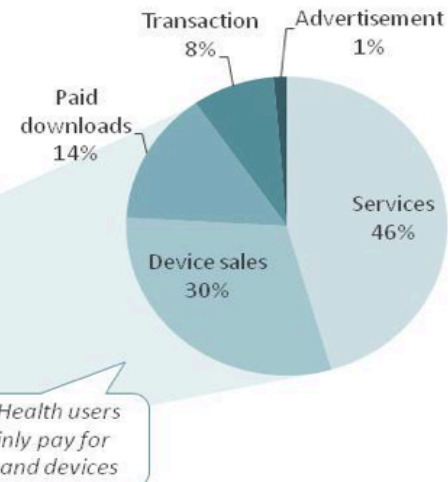


mHealth market 2015: 500m people will be using healthcare smartphone applications

Smartphone user base in 2015 (million)



Share of mHealth revenue sources of total mHealth market opportunity in 2010-2015 (%)



Smartphone applications will become the killer applications for mobile health solutions.

research2guidance

Global mobile health market report 2010-2015

<http://www.research2guidance.com/shop/index.php/mhealth-report>

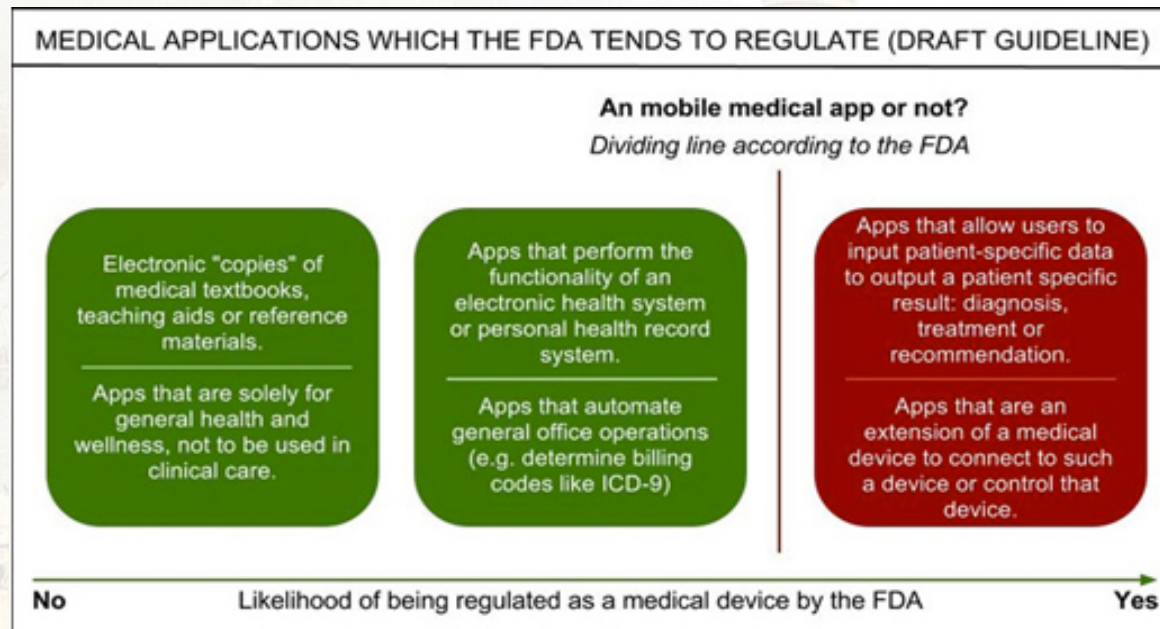


What makes a good quality app?

Who is it made by?

Is it evidence based? Has the content been reviewed?

Does it cross the line to being a medical device?



Draft US FDA guidelines



Glucose Buddy - Diabetes Helper 3.6.5 w/cross-device sync + BP/WT tracking

Description

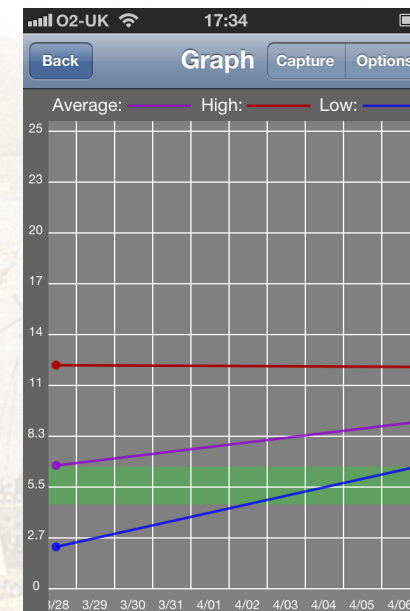
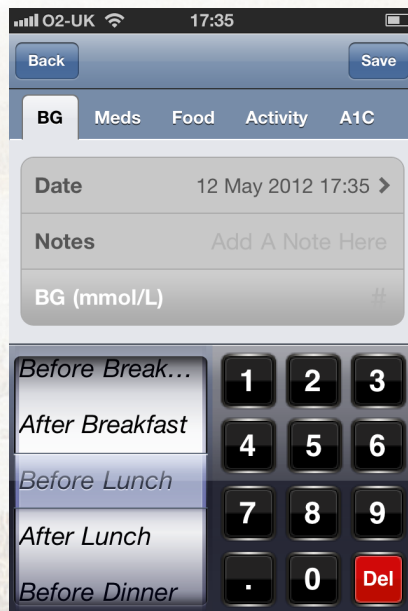
- Ranked #1 Diabetes iPhone Application by Manny Hernandez, Founder of TuDiabetes.com
- As seen in American Diabetes Association's Diabetes Forecast Magazine, NYTimes, Wired Magazine, DiabetesMine.com,...

[...More](#)

Cost: Free

Pros: Integrates with calorie track, forum, graph, log BG, activity, insulin

Cons: display, adverts, poor graph display





Carbs & Cals - A visual guide to Carbohydrate & Calorie Counting

Description

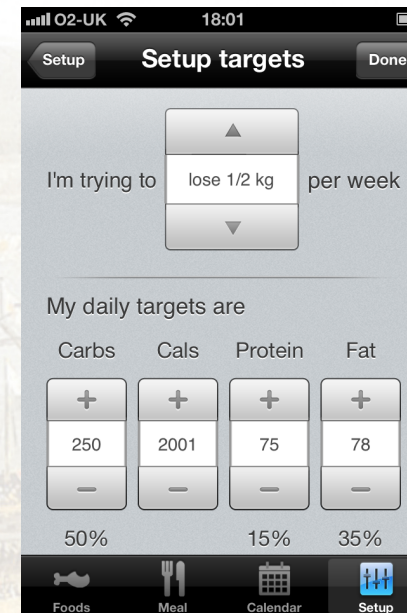
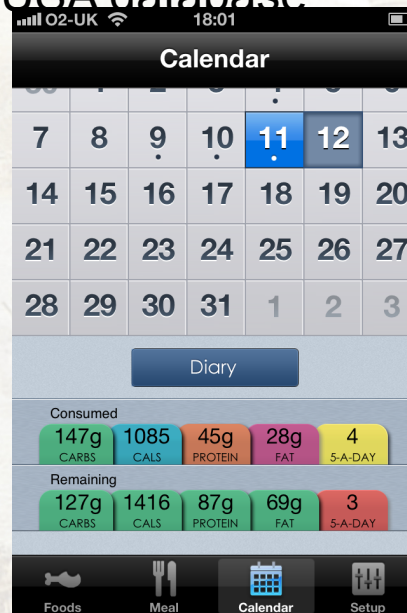
This is the Carbohydrate and Calorie Counting App you have always wanted! We've responded to user feedback, and it now contains over 1400 food & drink photographs so you can more easily judge the carbs and calories in your food and drinks th... [...More](#)

[Chello Publishing Web Site >](#) [Carbs & Cals - A visual guide to Carbohydrate & Calorie Counting Support >](#)

Cost: £3.99

Pros: Unique photographic database of foods, iPhone & Android (Blackberry very soon), growing database including branded foods, set up targets, log exercise

New features coming very soon include: recipe builder, barcode scanner, diabetes area, bolus advisor, USA database

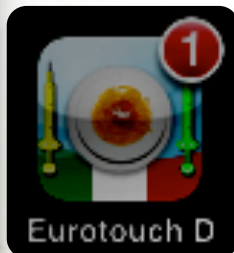




DID – Il Diaro Interattivo del

Diabete

è un software che può installato **iPhone**, **iPad** e **iPod Touch** con **firmware3**, che:



Supporta il paziente diabetico **insulino-trattato** nell'applicazione pratica della **conta dei carboidrati**

E' fornito di un setup per il calcolo del **bolo insulinico appropriato** e l'**aggiustamento immediato dell'insulina** in base alle variabili impostate dal diabetologo

E' predisposto per lo **scambio di informazioni** tra **paziente (iPhone)** e **diabetologo (Eurotouch)** in remoto (**Telemedicina**)

Il paziente inserisce il suo valore glicemico **1**



Il paziente può scegliere tra una vasta gamma di alimenti presenti in un database fotografico. Ogni porzione può essere personalizzata ed il paziente riceve in automatico il calcolo esatto del contenuto dei carboidrati. **2**



Adesso il diario interattivo contiene **tutti i dati** sull'alimentazione e sulla vita di Paola necessari per **calcolare il bolo insulinico** appropriato per la somministrazione. **3**

DID

Come funziona: le prescrizioni del Diabetologo

DIABETOLOG



Il Diabetologo, attraverso **EuroTouch**, riceve i dati e verifica il profilo glicemico del paziente e se lo ritiene opportuno, cambia l'algoritmo per il calcolo del suggerimento insulinico e aggiunge commenti in Note.

Prescrizioni di MARGHERITA età 18 (anni diabete 14)

Trattamento ipoglicemizzante 27/10/2005

27/10/2005 | 11/10/2005 | 04/10/2005 | 08/09/2005 | 01/09/2005 | 30/08/2005 | 30/08/2005 | 13/10/2005

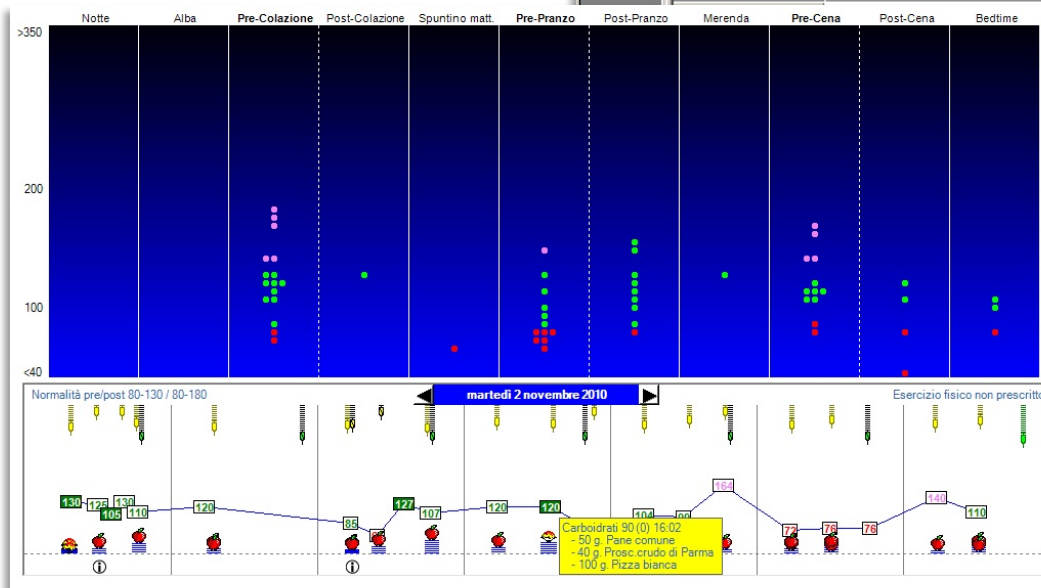
Microinfusori Solo Dieta Calcolatore di boli

Pasto	Tipo	Unità	U.I.
Colazione 6:00 - 9:00			
Spuntino matt.			
Pranzo 10:45 - 13:30			
Merenda			
Cena 16:30 - 20:30	Lantus®SC 5CART 3ML 100UI/ML	32	32,0

Calcolatore di boli: Humalog®SC 5Cart 100U/ml 3

Pasto	F. C.	I/CHO	Target Glic.
Pre-Colazione	30	6	100
Post-Colazione	30	6	140
Spuntino matt.	30	6	100
Pre-Pranzo	30	4	140
Post-Pranzo	30	4	100
Merenda	30	4	100
Pre-Cena	30	6	100
Post-Cena	30	6	140
Bedtime	30	6	110

totale unità prescritte nel giorno 32,0



Invio dei dati corretti al paziente.

Policy Implication

- Telemedicine program effective in diabetes monitoring & reducing diabetes related crisis
- Intervention program design more essential than technology in program success
- Telemedicine has the potential for larger scale community based tele-diabetes intervention
- Collaboration may involve organizations with interoperable personal health record systems
- Large scale intervention has the potential of efficiency of scale

Study Limitation

- Most of the studies reviewed enrolled sample sizes < 50 patients
- Nevertheless, irregular sample size & varied study designs did not permit comparison of intervention effectiveness that were context specific

Authors	Study group	Control group	Results
Di Biase et al (1997)	DIANET system	Regular ambulatory visits	1. Better metabolic control and higher insulin doses in the study group.
Frost et al (2000)	CareLink system	Regular ambulatory visits	1. No differences in HbA1c improvements between the two groups. 2. MBG and MFG markedly lower in the study group.
Wojcicki et al (2001)	Telematic Intensive Care system	Regular ambulatory visits	1. Better glycemic control in the study group, as assessed by MBG and J-index variations. 2. Significantly lower variations in the glycemic control indices applied in the study group.
Ladyzynsky et al (2001)	PTM and CCU system	---	1. Significant improvement in metabolic control
Ladyzynsky et al (2007)	Home Telecare system	Clinical examinations every 3 weeks	1. Similar levels of metabolic control and insulin adjustment in the two groups

Table 1. Brief outline of the studies conducted on telemedicine for type 1 diabetes mellitus in pregnancy

Authors	Study group	Control group	Results
Hernando et al (2000)	DIABNET system	---	Two different experiments evaluated the system's performance compared to physicians, based on answers to questionnaires and quantitative comparisons of the system's and experts' recommendations
Pérez-Ferre et al (2009)	Telemedicine system (Internet and text messages)	Traditional face-to-face visits at the outpatient clinic	1. Women in the study group went significantly less to the outpatients clinic. 2. No differences in HbA1c levels between the two groups 3. No significant differences in delivery modality between the two groups 4. No difference in the rate of LGA babies between the two groups
Homko et al (2007)	Telemedicine system (website for recording of glucose values)	Information recorded in a paper logbook	1. No differences between the two groups regarding fasting or after-meals glucose values 2. No significant differences in pregnancy or neonatal outcomes 3. Study group patients had stronger "feelings of self-efficacy"

Table 2. Short outline of studies on telemedicine for pregnancies complicated by gestational diabetes mellitus (GDM)

Telemedicine in Pregnancy Complicated by Diabetes

Annunziata Lapolla, Nino Cristiano Chilelli and Maria Grazia Dalfrà

**In: "Advances in Telemedicine: Applications in Various Medical Disciplines and Geographical Regions", 2011 InTech ED., ISBN: 978-953-307-161-9
AUTORI: Georgi Graschew and Theo A. Roelofs**

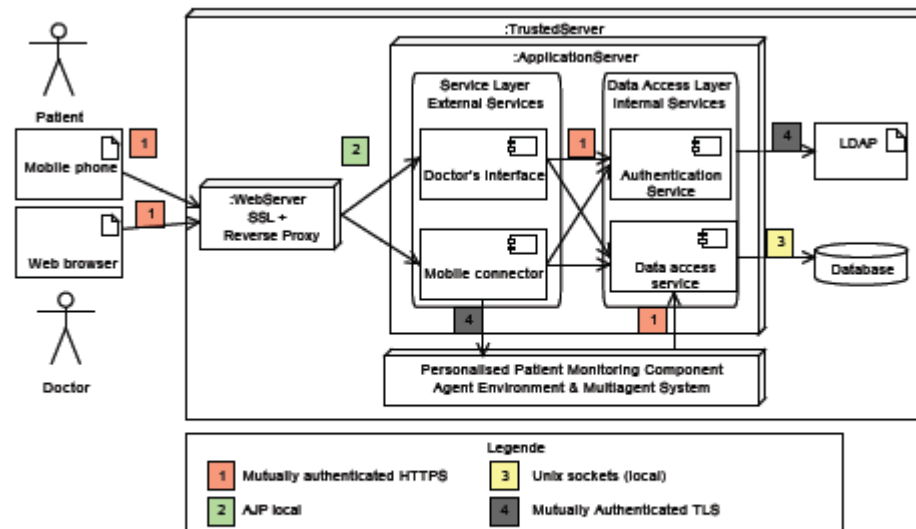


Figure 3. Security of the GDMM system

eTELEMED 2012 : The Fourth International Conference on eHealth, Telemedicine, and Social Medicine

Enforcing Security in Pervasive Healthcare Monitoring Gestational Diabetes Mellitus

Stefano Bromuri, Johannes Krampf, René Schumann, Michael Ignaz Schumacher

Institute of Business Information Systems,

University of Applied Sciences Western Switzerland,

Emails: stefano.bromuri@hevs.ch {johannes.krampf, rene.schumann, michael.schumacher}@hevs.ch

Impact of a Telemedicine System with Automated Reminders on Outcomes in Women with Gestational Diabetes Mellitus

Carol J. Homko, R.N., Ph.D., C.D.E.,^{1,2,3} Larry C. Deeb, M.D.,^{4,5} Kimberly Rohrbacher, R.N., C.D.E.,⁴
Wadia Mulla, M.D.,³ Dimtrios Mastrogiannis, M.D.,³ John Gaughan, Ph.D.,⁶
William P. Santamore, Ph.D.,⁶ and Alfred A. Bove, M.D., Ph.D.¹

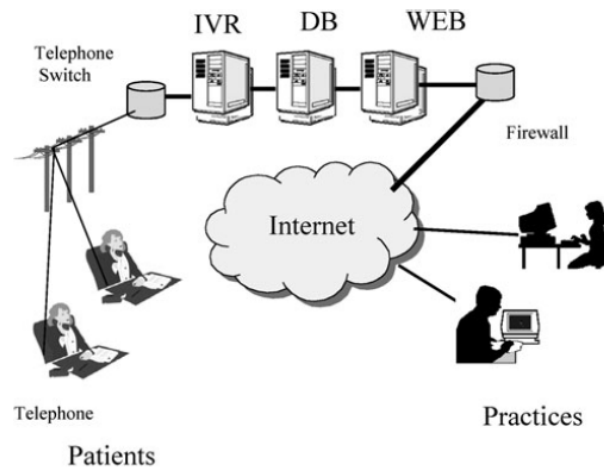


FIG. 1. Schematic representation of the integrated Internet-based informatics application and interactive voice response (IVR) system. DB, database.

In summary, our enhanced telemedicine monitoring system increased contact between women with GDM and their healthcare providers but did not impact upon pregnancy outcomes. The expectation that such systems may lead to improved control and outcomes among pregnant women with GDM may be unrealistic. However, the real potential of these emerging healthcare technologies may be their ability to increase efficiency while maintaining the quality of care. Future studies should focus on these issues as well as the impact of health technology on patient satisfaction with treatment.

The effect of **telemedicine** on outcome and quality of life in pregnant women with **diabetes**.

Dalfrà MG, Nicolucci A, Lapolla A; and TISG
J Telemed Telecare. 2009;15(5):238-42.

Clinical variables and pregnancy outcomes were no different between the two telemedicine groups, whereas women with gestational diabetes in the telemedicine group had a better metabolic control in the 3rd trimester and a lower rate of caesarean sections and macrosomia. As for QoL, women in the telemedicine groups showed lower levels of frustration and concerns about their diabetes, and a better acceptance of their diabetic condition.



Home Uterine Activity Monitor



Non Stress Test Home Monitor



Obstetrical hypertension management



[Vantaggi clinici dell'utilizzo di cartelle elettroniche](#)

Fonte: Ann Intern Med. 2 October 2012; 157(7): 482-489.

I medici americani possono ricevere incentivi federali per l'utilizzo di pacchetti e cartelle cliniche elettroniche certificate (EHR). Tali applicativi possono intervenire efficacemente nei processi di cura e di controllo della malattia nei pazienti con diabete.



Conclusioni

- I sistemi di monitoraggio glicemico e di terapia utilizzati nella cura delle persone con diabete possono essere utilizzati in gravidanza con efficacia.
- Non esistono modelli educativi, fondati sulle nuove tecnologie, dedicati alla gravidanza.
- Con l'incremento progressivo dei costi del SSN è opportuno "esplorare" alternative di cura che possono risultare più economiche
- La telemedicina nelle gravidanze ad alto rischio sembra essere "cost effective".
- Uno studio di Morrison et al (2001) conclude che "each pregnancy in the telemedicine group cost an average of \$7,225 compared to the \$21,684 cost to those who did not receive outpatient services".
- Secondo Matria Healthcare, assicurazione USA, "for each \$1 spent in home preterm management services, \$3 to over \$5 is saved by reducing antepartum and neonatal nursery days."
- Il costo dei sistemi attuali è ribaltato quasi esclusivamente sulle pazienti
- Non esistono RCT su grandi numeri di pazienti
- Non è stato individuato un modello unico di piattaforma
- Devono ancora essere risolti i problemi legati alla sicurezza dei sistemi