# Electronic devices for clinical data

## Dispositivi elettronici e clinical data

**B. Pintaudi**[1]

basilio.pintaudi@ospedaleniguarda.it

## SUMMARY

Electronic devices are useful tools for understanding diabetes-related mechanisms and phenomena and, more importantly, for improving the level of disease management. They can be important in quality of care programs allowing to speed up the process of data measurement. The aim of quality of care initiatives is to measure the clinical activity in order to find specific area for improving the level of care. They are based on the use of "quality indicators" (structural, process and outcome indicators), a series of parameters by which the extent of quality of care can be ascertained. Most of the studies on quality of care have involved type 1 or type 2 patients, women with diabetes in pregnancy (both pre-gestational and gestational) being excluded. At international level few initiatives aiming to investigate the level of caring pregnant women with diabetes exist. In Italy the Plan on diabetes, an official document written by the National Commission on Diabetes of the Italian Ministry of Health, recommends to reach perinatal and maternal outcomes similar to those of pregnancies not complicated by diabetes. Among possible strategies to reach this objective data collection and its analysis was suggested. In this line a new initiative is promoted by the Italian Diabetes and Pregnancy Study Group. Its name is "Gravidanza Italia" and it will involve diabetes Centers at a national level. The project includes several phases: creation of a network of diabetes centers with the same electronic medical record; identification of pregnancy-specific indicators; development of a Pregnancy Data File; data extraction and periodic sending of Pregnancy Data File; centralized analysis of the data and their publication; benchmarking activities. The project will describe the profiles of care of pregnant women with gestational and pre-gestational diabetes in Italy in order to provide a tool for improving the quality of care.

1 S.S.D. Diabetologia, ASST Grande Ospedale Metropolitano Niguarda.

## RIASSUNTO

I dispositivi elettronici sono strumenti utili per la comprensione dei meccanismi e dei fenomeni legati al diabete e, soprattutto, per migliorare il livello di gestione della malattia. Essi possono essere importanti nei programmi di qualità di cura consentendo di accelerare il processo di rilevamento dei dati. Scopo delle iniziative incentrate sulla qualità di cura è quello di misurare l'attività clinica per trovare determinate aree di miglioramento del livello di assistenza. Essi si basano sull'uso di "indicatori di qualità" (strutturali, di processo e di esito), una serie di parametri attraverso cui il grado di qualità delle cure può essere constatato. La maggior parte degli studi sulla qualità di cura hanno coinvolto pazienti con diabete di tipo 1 o di tipo 2, mentre le donne con diabete in gravidanza (sia pre-gestazionale che gestazionale) sono state il più delle volte escluse. A livello internazionale esistono poche iniziative volte ad indagare il livello di cura di donne gravide con diabete. In Italia il Piano sul diabete, un documento ufficiale prodotto dalla Commissione Nazionale sul Diabete del Ministero della Salute, raccomanda di ottenere esiti perinatali e materni simili a quelli delle gravidanze non complicate da diabete. Tra le possibili strategie per raggiungere tale obiettivo è stata suggerita la raccolta di dati e la loro analisi. In questa linea una nuova iniziativa è stata promossa dal Gruppo di studio italiano diabete e gravidanza. Il suo nome è "Gravidanza Italia" e coinvolgerà i centri di diabetologia a livello nazionale. Il progetto prevede diverse fasi: la creazione di una rete di centri di diabetologia con la stessa cartella clinica elettronica; l'identificazione di indicatori specifici per la gravidanza; lo sviluppo di un File Dati Gravidanza; l'estrazione dei dati e l'invio periodico del File Dati Gravidanza; l'analisi cen-

tralizzata dei dati e la loro pubblicazione; attività di benchmarking. Il progetto descriverà i profili di cura delle donne in gravidanza con diabete gestazionale e pre-gestazionale in Italia al fine di fornire uno strumento utile a migliorare la qualità delle cure.

**Parole chiave** Dispositivi elettronici, Qualità di cura, Diabete in gravidanza

In recent years new electronic devices have represented a useful tool for understanding diabetes-related mechanisms and phenomena and, more importantly, for improving the level of disease management[1]. Continuous glucose monitoring systems, insulin pumps, instruments for self monitoring blood glucose, e-health platforms, telemedicine systems changed the perspective of diabetes care. All these devices allow to catch a lot of information on clinical parameters. A growing need for information on clinical data should be recognized. Big data represent a significant source that can give clinical answers faster and more consistently than single clinical studies[2]. The analysis of clinical data can be finalized to different aims. It can be important for data management, research projects, funding allocation, education and other purposes.

However, one of its main utility on the part of health care professionals is allowing to measure each own clinical activity in order to find specific area for improving the level of care. This is the core of all the initiatives in the field of quality of care. In this context the use of electronic devices can speed up the process of measurement by avoiding the waste of time needed for data achievement.

In the last decades several international health organizations, both public and private, have promoted initiatives focused on measuring and improving the quality of care in people with diabetes. They are based on the use of "quality indicators", a series of parameters by which the extent of quality of care can be ascertained. We can distinguish between three kinds of indicators: structural, process and outcome indicators. The first are represented by all structural and organizational aspects of the Centers and health care providers' characteristics. Process measures are all the diagnostic, preventive, curative and rehabilitative implemented procedures. Finally, outcome measures define those parameters that allow to assess changes, favorable or adverse, in the state of health of a person, group or community, that can be attributed to the received assistance. It is possible to make a distinction between intermediate outcome measures, that are short-term assessments of changes in the quality of care of the patient, and final outcome measures, that are long-term evaluations. Quality of care has been studied and evaluated in diabetes settings[3,4]. At international level there are both cross-sectional and prospective studies that have assessed the level of care comparing to standard references[5,6]. In Italy since 2006 an important ongoing initiative that is called AMD Annals exists. This initiative is mainly focused on quality of care[7,8]. Trends over 8 years in quality of diabetes care resulting from the AMD Annals continuous quality improvement initiative showed a progress in quality of diabetes care[9]. One of the main advantage of AMD Annals is that it represent a physician-led effort not requiring allocation of extra-economic resources, which is easy to implement and deeply rooted in routine clinical practice. Most of the studies on quality of care have involved type 1 or type 2 patients, women with diabetes in pregnancy (both pre-gestational and gestational) being excluded. At international levels we can find few initiatives aiming to investigate the level of caring pregnant women with diabetes. One of the first similar initiative was the DIABCARE Quality Network in Europe, a model for quality management in chronic diseases including diabetes in pregnancy[10-12]. Its main aim was to monitor the targets of the St Vincent Declaration and the implementation of quality management in diabetes care. However, despite the important design and scope its diffusion was limited in the time. Maybe the first pregnancy-oriented initiative was the OBStetrical Quality Indicators and Data collection (OBSQID) project, a pan-European network of researchers, healthcare providers, professional institutions and associations using agreed key quality indicators and served by a common database[13]. OBSQID was based on the general concept of continuous assessment, management and development of quality of care and was geared to perinatal medicine. It identified 'best practices' and allowed for the exchange and transfer of knowledge and expertise through 'twinning' or collaborative partnerships. With the aim to compare the use of paper, standalone and networked electronic processes for a sustainable, systematic international audit of diabetes in pregnancy care the Australian ADIPS pilot National Diabetes in Pregnancy Audit Project was promoted[14]. More recently in UK the North West Diabetic Pregnancy Audit was performed[15]. These annual audit reports allow the assessment of current management and outcomes for diabetic pregnancies at a regional and local level. The data collection methodology implied the required participation of a data

collection coordinator and a responsible individual in each diabetes unit who had to notify new diabetes in pregnancy cases and to record the outcomes of the pregnancy once it was completed. This initiative was started with great enthusiasm, however, barriers to data collection in routine care were recognized[16]. In particular logistical challenges, limited resources and poor IT infrastructures were the main problems. Having the possibility to obtain data automatically could represent a way to solve all the problems linked to the data collection.

In Italy in 2013 the Plan on diabetes, an official document written by the National Commission on Diabetes of the Italian Ministry of Health, was published[17]. The most important goal for gestational diabetes and diabetes in pregnancy recommended by the Plan is "to reach perinatal and maternal outcomes similar to those of pregnancies not complicated by diabetes". Among possible strategies to reach this objective data collection and its analysis was suggested by the Plan. Following on the recommendations of the National Plan the need to describe the profiles of care of pregnant women with gestational and pre-gestational diabetes in Italy, in order to provide a tool for improving the quality of care, has been recognized. In this line a new initiative is now promoted by the Italian Diabetes and Pregnancy Study Group. Its name is "Gravidanza Italia" and it will involve diabetes Centers at a national level. The project includes several phases:

- Creation of a network of diabetes centers with the same electronic medical record;
- Identification of pregnancy-specific indicators;
- Development of a Pregnancy Data File;
- Data extraction and periodic sending of Pregnancy Data File;
- Centralized analysis of the data and their publication;
- Benchmarking activities.

In Italy most of diabetes centers use the same electronic clinical record. Among them almost 130 diabetes centers use a specific section of the electronic clinical record that is dedicated to pregnancy. It allows to record information on several pregnancy-related parameters: laboratory tests, anthropometric measures, risk factors for the development of GDM and diagnostic test for its detection, fetal ultrasound parameters, therapy, fetal outcomes. It is important to emphasize that the quality of care measured with medical records is affected by the level of completeness and accuracy with which information is recorded. Moreover, the lack of information is to itself a bad quality of care indicator.

Pregnancy-specific indicators are represented by descriptive, process, intermediate outcome and final outcome indicators. Some examples of these indicators are reported in tables 1-4. One of the main difference between initiatives of quality of care involving pregnant women compared to those involving subjects out of pregnancy is that pregnancy allows to collect data on final outcomes that is very limited in type 1 or type 2 diabetes.

**Table 1** Pregnancy-specific descriptive indicators.

| |
|---|
| Number of GDM cases on total women screened |
| Number of T1D pregnant cases on total women screened |
| Number of T2D pregnant cases on total women screened |
| Mean age of the cared population |
| Distribution of the cared population according to parity |
| Distribution of the cared population according to the number of risk factors for GDM at 16-18 gestational weeks |
| Distribution of the cared population according to the number of risk factors for GDM at 24-28 gestational weeks |
| % of patients with OGTT performed at 16-18 gestational weeks resulted positive for GDM |
| % of patients with OGTT performed at 24-28 gestational weeks resulted positive for GDM |
| Distribution of the cared population according to the altered OGTT glucose value |
| Mean HbA1c levels |

**Table 2** Pregnancy-specific process indicators.

| Distribution of the cared population with T1d and T2D according to the glucose-lowering treatment (before, during and after pregnancy) |
|---|
| Distribution of the cared population according to the antihypertensive treatment |
| Number of visits per year according to treatment |
| Mean duration of insulin treatment |
| Mean number of insulin units a day |
| Women performing self-monitoring blood glucose (mean number of tests a day) |
| Mean number of HbA1c tests |
| Mean number of BP measurements |
| % of patients with GDM who performed f-up OGTT within one year after delivery |
| % of women with GDM or T2D who continue insulin after delivery |
| Women with T1D o T2D screened for urinary albumin |
| Women with T1D o T2D screened for retinopathy |

**Table 3** Pregnancy-specific intermediate outcome indicators.

| Mean HbA1c levels |
|---|
| Mean HbA1c levels according to treatment |
| Mean HbA1c levels according to age classes |
| Women with T1D or T2D with HbA1c levels <= 7.0% before pregnancy |
| Women with T1D or T2D with HbA1c levels <= 7.0% during pregnancy |
| Women with T1D or T2D with HbA1c levels <= 7.0% after pregnancy |
| Women with BP < 140/90 mmHg |
| Hypertensive women with BP < 140/90 mmHg |
| Women with BP >= 140/90 mmHg in treatment |
| Women with BP >= 140/90 mmHg not in treatment |
| Mean LDL-cholesterol levels |
| Women with LDL-cholesterol levels < 100 mg/dl |
| Women with LDL-cholesterol levels >= 130 mg/dl |
| % of women with albuminuria before and during pregnancy |

**Table 4** Pregnancy-specific final outcome indicators.

| Large for Gestational Age (LGA) |
|---|
| Small for Gestational Age (SGA) |
| Neonatal hypoglicemia |
| Cesarean delivery |
| NICU admission |
| Gestational hypertension |
| Preeclampsia |
| Eclampsia |
| Stillbirth |
| Gestational week of the delivery |
| Amniotic fluid alteration |
| Malformation |
| Mortality rate |
| Final outcomes according to insulin therapy |

To build the indicators it is essential having information on several parameters collected in the electronic medical records. With this purpose the Pregnancy Data File, which is a standardized set of data flow from electronic medical records has been developed. It is made by specific parameters present in the electronic medical records to which a unique code, the relative unit of measurement in the case of anthropometric or laboratory data, the type (numeric or text), the size of the field, the format and the range of plausible values, the ICD-9 code in the case of procedures or the ATC code in the case of fields indicating drugs have been assigned. Therefore the Pregnancy Data File represents an essential tool by which it is possible to translate the clinical information contained in the electronic medical record in a statistically analyzable format.

All the involved diabetes Centers will give their data which will be aggregated and analyzed anonymously. The entire project will lead to scientific publications. The impact of this initiative will be great for several reasons. First, it will represent a national picture of the level of care of pregnant women with pre-gestational diabetes and with GDM. Second, starting from the actual level of care each diabetes Center will be able to improve their attention in caring for these women. Third, it will give a strong tool to stakeholders for healthcare plans and benchmarking initiatives. The analysis of clinical data is a need now and will be increasingly important in the near future. Healthcare providers should understand this and should integrate smart electronic devices in their clinical practice. Only the measurement and the benchmarking will lead to more favorable outcomes and consequently to a better level of care.

## CONFLICT OF INTEREST

Nothing to declare.

## BIBLIOGRAPHY

1. Garvey K, Wolfsdorf JI. The Impact of Technology on Current Diabetes Management. Pediatr Clin North Am 62(4):873-88, 2015.

2. Kessel KA, Combs SE. Review of Developments in Electronic, Clinical Data Collection, and Documentation Systems over the Last Decade – Are We Ready for Big Data in Routine Health Care? Front Oncol 6:75, 2016.

3. Fleming BB, Greenfield S, Engelgau MM, Pogach LM, Clauser SB, Parrott MA. The Diabetes Quality Improvement Project: Moving science into health policy to gain an edge on the diabetes epidemic. Diabetes Care 24:1815-20, 2001.

4. Tricco AC, Ivers NM, Grimshaw JM, Moher D, Turner L, Galipeau J, Halperin I, Vachon B, Ramsay T, Manns B, Tonelli M, Shojania K. Effectiveness of quality improvement strategies on the management of diabetes: a systematic review and meta-analysis. Lancet 379(9833):2252-61, 2012.

5. Peters AL, Legorreta AP, Ossorio RC, Davidson MB. Quality of outpatient care provided to diabetic patients. A health maintenance organization experience. Diabetes Care 19(6):601-6, 1996.

6. Saaddine JB, Cadwell B, Gregg EW, Engelgau MM, Vinicor F, Imperatore G, Narayan KM. Improvements in diabetes processes of care and intermediate outcomes: United States, 1988-2002. Ann Intern Med 144(7):465-74, 2006.

7. Rossi MC, Nicolucci A, Arcangeli A, Cimino A, De Bigontina G, Giorda C et al.; Associazione Medici Diabetologi Annals Study Group. Baseline quality-of-care data from a quality-improvement program implemented by a network of diabetes outpatient clinics. Diabetes Care 31:2166-8, 2008.

8. Nicolucci A, MC Rossi, Arcangeli A, Cimino A, de Bigontina G, Fava D et al. Four-year impact of a continuous quality improvement effort implemented by a network of diabetes outpatient clinics: The AMD-Annals initiative. Diabet Med 27:1041-8, 2010.

9. Rossi MC, Candido R, Ceriello A, Cimino A, Di Bartolo P, Giorda C, Esposito K, Lucisano G, Maggini M, Mannucci E, Meloncelli I, Nicolucci A, Pellegrini F, Scardapane M, Vespasiani G. Trends over 8 years in quality of diabetes care: results of the AMD Annals continuous quality improvement initiative. Acta Diabetol 52(3):557-71, 2015.

10. Piwernetz K, Home PD, Snorgaard O, Antsiferov M, Staehr-Johansen K, Krans M. Monitoring the targets of the St Vincent Declaration and the implementation of quality management in diabetes care: the DIABCARE initiative. The DIABCARE Monitoring Group of the St Vincent Declaration Steering Committee. Diabet Med 10(4):371-7, 1993.

11. Gerlach K, Kaeding A, Kottmair S, Westphal D, Henning G, Piwernetz K. The implementation of a quality-net as a part of the European project DIABCARE Q-Net. IEEE Trans Inf Technol Biomed 2(2):98-104, 1998.

12. Piwernetz K. DIABCARE Quality Network in Europe – a model for quality management in chronic diseases. Int Clin Psychopharmacol 16 Suppl 3:S5-13, 2001.

13. Johansen KS, Hod M. Quality development in perinatal care – the OBSQID project. OBStetrical Quality Indicators and Data. Int J Gynaecol Obstet 64(2):167-72, 1999.

14. Simmons D, Cheung NW, McIntyre HD, Flack JR, Lagstrom J, Bond D, Johnson E, Wolmarans L, Wein P, Sinha AK; ADIPS National Diabetes in Pregnancy Audit Project Team. The ADIPS pilot National Diabetes in Pregnancy Audit Project. Aust N Z J Obstet Gynaecol 47(3):198-206, 2007.

15. Young RJ, Holmes EM, Casson IF, Maresh M. The North West Diabetic Pregnancy Audit: a practical system for multi-centre diabetic pregnancy audit. Diabet Med 25(4):496-500, 2008.

16. Murphy HR, Bell R, Holt RI, Maresh M, Todd D, Hawdon J, Young B, Holman N, Hillson R, Lewis-Barned N; National Pregnancy in Diabetes Audit Steering Group. The National Pregnancy in Diabetes Audit: measuring the quality of diabetes pregnancy care. Diabet Med 30(9):1014-6, 2013.

17. Ministero della Salute – DG Programmazione Sanitaria – Commissione Nazionale Diabete. Piano sulla malattia diabetica. http://www.salute.gov.it/imgs/C_17_pubblicazioni_1885_allegato.pdf.