Puglia, Italy: DIAMONDS - Digital Assisted MONitoring for DIabeteS

Part 1: General Information

Publication on EIP on AHA Portal	Yes
Copyright	Yes
Verification of the Good Practice	No
Evaluation of the Good Practice	Yes
Type of the Good Practice	Notable practice

Part 2: Description of the Good Practice

Name of the Good Practice	Digital Assisted MONitoring for DiabeteS
Short name (Acronym)	DIAMONDS
URL of the Good Practice	Not available
Geographical scope	Regional level
Country	Italy
Region(s) involved	Apulia (Puglia)
Status of the Good Practice	On-going
Stakeholders involved	• Hospitals • Research centres • Academia • Specialised physicians • General practitioners • Nurses • Pharmacists • National public authorities • Regional pubic authorities • WHO • Large-sized industry • Primary care centres • Private companies • Advocacy organisations of physicians
Size of population covered	10,000-99,999
Targeted audience	18-49; 50-64; 65-79

Summary of the Good Practice

The practice aims to validate the clinical efficacy of a telemedicine- and web-based system platform for self- monitoring of blood glucose (SMBG) data transmission and analysis of metabolic control, assessed by measuring changes inHbA1c, in insulin-treated diabetic patients. The system platform involves (i.) systematic (real-time and anywhere) transmission of SMBG data to a decision supported software (DSS)-assisted server, (ii.) web-

based analysis of data, and (iii.) feedback on patients and medical staff to implement metabolic control. Additional aims include assessments of patients' adherence to perform SMBG, analysis of the specific and overall quality of glucose control, identification of situations predictive of hypoglycaemic and/or hyperglycaemic episodes, and detection of episodes of hypoglycaemia and sustained hyperglycaemia.

It is to be expected that use of the telemedicine- and web-bases system platform will result in improved metabolic control as compared with standard of care, as shown by a greater decrease in HbA1c from baseline. In addition, it will potentially result in better quality of glucose monitoring and control (e.g., appropriateness of SMBG testing, glucose excursions, indexes of glucose variability) and frequency and severity of hypoglycaemic episodes. Also, quality of life should be improved in the telemedicine group. Thus, patients and physicians will be provided with a tool that allows to verifying the appropriateness of SMBG in relation to the diabetes status, and this will be also relevant to "payers" (false glucose reporting and data collection will be avoided, patient/physician interaction will be optimized while limiting the number of medical visits).

Key words: diabetes mellitus, self-monitoring of blood glucose, insulin therapy, digital transmission, decision supported software

Good practice being part of the larger programme

Yes.

Additional practices are ongoing or have been already validated in specific cohorts of patients with diabetes and nephropathy, and diabetes and cardiovascular diseases.

Challenges / problems addressed by the good practice

1. Provide patients and physicians with a tool that allows to verify the appropriateness of SMBG in relation to the diabetes status.
2. Analyze the quality of glucose control with new parameters (extent of hyper/hypoglycaemia episodes, risk of hyper/hypoglycaemia, glucose levels related to meals, hyper/hypoglycaemia episodes and emergencies).
3. Provide immediate feed-back to the patient to manage severe hypoglycaemia/ hyperglycaemia.
4. Provide patient with detailed information on glucose data which may strengthen perception of diabetes control.
5. Avoid false glucose reporting and data collection.

Importance of the challenges / problems before starting to implement good practice

1. Execution of SMBG often is carried out without being conform to current guidelines (e.g., less frequent or more frequent than recommended).
2. Patients with diabetes, especially insulin-treated, often show inadequate glucose control due to episodes of hyper/hypoglycaemia, and emergencies.
3. Patients are often alone while managing severe hypoglycaemia/ hyperglycaemia.

4. Patients need information on glucose data which may strengthen their perception of diabetes control and adherence to therapy – adherence to diabetes therapy is by far suboptimal. 5. Patients report false glucose data related to SMBG in 25-30% of cases.
Environment before the good practice was implemented Patients with diabetes on insulin therapy rely on SMBG to identify states of inadequate glucose control and adjust therapy. They often test themselves too frequently or less than recommended, generating a significant waste of glucose strips or lack of accurate information on their glucose levels, respectively. Furthermore, such patients are at high risk of hypoglycaemia and are alone when such episodes occur with significant including life-threatening risks. Improvement of glucose control in type 1 and type 2 diabetic patients on insulin-therapy is largely needed (>50% show HbA1c levels >7%). Adherence to diabetes therapy is less than optimal and currently averages around 60% in patients taking insulin injections. Another problem is that patients may report false glucose data while performing SMBG due to fear or non-acceptance of the diseases (25-30% of cases according to recent reports). This is a further barrier to achieving an adequate glucose control.
Key innovative elements of the good practice and how the good practice improved situation compared to previous practice 1. Allowed to verify the appropriateness of SMBG in relation to the diabetes status and to identify a significant proportion of patients not performing SMBG according to current guidelines. 2. Enabled timely (real-time) identification of patients with uncontrolled diabetes before the scheduled visit, as well as patients at risk of hyper/hypoglycaemia and specific hypoglycaemia emergencies. 3. Provided immediate feedback to the patient to manage severe hypoglycaemia/hyperglycaemia. 4. Provided patients with detailed information on glucose data which may strengthen perception of diabetes control. 5. Avoided false glucose reporting and generated data collection suitable for scientific analyses.

Part 3: Transferability of the Good Practice

Cost-effectiveness of the good practice (including all kind of costs and outcomes such as better health, quality of life or other resources)	Equal costs, deteriorated outcomes

Resources required for the deployment of the good practice (personnel, equipment, facilities, ICT and other resources required)

Patients using the practice perform SMBG using a smartphone-connected glucometer modified for USB cable connection to smartphone. The smartphone is implemented with a software for real-time collection and transmission of measured glucose values to the remote server. Thus, the glucometer is made «hot» for real-time and anywhere data transmission. In addition, at the time of blood glucose measuring, the patient enters information on whether the measurement is being performed in the pre-prandial, post-prandial or absorptive periods, and indicates which meals the measurement refers to (i.e., breakfast, lunch, dinner, snack). SMBG results are immediately transmitted to the remote server, which performs data collection and analysis, and provides feedback to the patient and the medical staff according to pre-defined specific algorithms (Decision Supported Software, DSS). Thus, states of inadequate glucose control can be identified, and the contacts between the patients and the diabetes medical team are intensified via SMS and/or phone calls. A specific algorithm, which has been incorporated into the DSS, allows the patients to self-calculate the dose of basal insulin to be administered according to the measured fasting blood glucose levels for consecutive periods of three days. Glucose data and analyses are made accessible to the patients and medical staff anytime and anywhere via the web. Patients are also assisted by the diabetes medical team located at or connected with a call centre (24-hours/day, 7 days/week), which is alerted by the DSS-supported server in case of emergencies (e.g., severe hypoglycaemia).

Total budget of the Good Practice	€100.00-€499,999
Source of funding	Private funding

The main actions that have to be done to deploy the Good Practice

Patients have to be followed through a web-based electronic CRF (GlucoonlineTM eCRF), thus the medical staff has to be instructed to periodically check the GlucoonlineTM eCRF and be also automatically alerted by the DSS-supported server when specific patients (i.) perform SMBG sub-optimally (e.g., too infrequent or temporally inadequate testing), (ii.) show poor glucose control, (iii.) go beyond thresholds set for hypoglycaemia/hyperglycaemia (e.g., too many glucose values off target within a specific time frame), (iii.) experience severe hypoglycaemia or sustained hyperglycaemia. Under these conditions, irrespective of the planned study visits, the medical staff can make appropriate interventions, including patient counselling via phone/SMS or arrange a medical visit if needed. If a patient has SMBG value <40 mg/dl, he/she receives an SMS on the smartphone with instructions on how to correct hypoglycaemia; the medical team potentially phones the patient or have an emergency car go to the patient's site (free public health service available in Italy) if needed and depending on the severity and evolution of the hypoglycaemic episode. All patients undergo an educational session to ascertain that they adequately perform SMBG. They need to learn how to (i.) use the glucometer/smartphone platform, (ii.) access their personal GlucoonlineTM eCRF on the web and visualize selected information on their glucose control, (iii.) interpret specific glucose abnormalities, and (iv.) refer themselves to the medical staff irrespective of the

planned study visits if needed, (iv.) use of the DSS-delivered algorithm to self-titrate the dose of basal insulin on the basis of fasting blood glucose levels.
Issues during the implementation of the Good Practice 1. Finding adequate financial support. 2. Motivating patients to use the new practice before enrolment. 3. Performing long-term follow-up of the patients, since they tend to be less motivated over time.
Additional resources required to scale up Good Practice Yes. The practice can be scaled up provided that there is adequate financial support to purchase new devices and to recruit medical personnel and nurses to educate and follow-up the patients. There is no need to acquire different instrumentation or higher-level systems of work organisation, since the practice allows scaling up in a modular fashion.
Basis to support sustainability of the Good Practice The practice was already shown to be feasible on a cohort of 200 insulin-treated patients with type 1 or type 2 diabetes where the expected outcomes have been largely achieved. Even though the practice has higher costs due to purchasing of the devices, software setting-up/customisation and personnel recruitment (€750 per patient/year), it may translate into significantly lower costs due to savings from improved outcomes (better glucose control translates into fewer diabetes complications), appropriateness of SMBG performance and fewer hospitalisations (e.g., due to hypoglycaemia). This is particularly relevant considering that the practise is intended at the moment to be offered to insulin-treated patients with diabetes who are at high risk of hypoglycaemia. In the Apulian region during the period 2002-2010 - 385,527 subjects, 92% with type 2 diabetes, underwent 10,362 hospitalisations due to severe hypoglycaemia, with a total cost of € 31,256,985 (average cost per patient: € 3,016).
Evidence to observe the Good Practice A practice report A webpage A visit to an implementation site http://www.diamonds-trial.net/diamonds/

Part 4: Viability assessment of the Good Practice

Time needed to deploy the Good Practice Less than a year. 1. Meetings with local health authorities to assess interest in the new practice.

2. Involvement of industries producing glucometers.
3. Meetings with specialized physicians and nurses.
4. Meetings with patients' organisations.

Investment per citizens / patient / client in terms of financial resources

Between €100 – €1.000 per targeted citizen / patient.

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Evidence behind the Good Practice

Documented evidence. Evidence is based on systematic qualitative and quantitative studies.

We have recently developed a telemedicine system [Glucoonline®, 2011], which consists of a smartphone-connected glucometer, a software- implemented smartphone for real-time and anywhere blood glucose data collection and transmission to a remote server, and a Decision Supported Software (DSS)-assisted server capable of performing data collection and analysis, and providing feed-back to the patient and the medical staff according to pre-defined specific algorithms. A pilot study showing the feasibility of using this system in 10 individuals with type 1 diabetes treated with a multiple daily injection (MDI) regimen over a 3-month period has been already carried out [Giorgino F, data on file]. A clinical trial using this system is running (Clinicaltrials #NCT01804803) to assess its efficacy in insulin-treated individuals with type 1 or type 2 diabetes mellitus. Interim analyses have been carried out, which show satisfactory outcomes in terms of improved metabolic control, assessed by measuring changes inHbA1c, improved patients' adherence to perform SMBG according to current guidelines, improved specific and overall quality of glucose control, and detection of episodes of hypoglycaemia and states of sustained hyperglycaemia.

Maturity of the Good Practice

There is evidence that the practice is economically viable and brings benefits to the target group. Further research and development is needed in order to achieve market impact and for the practice to become routine use.

Estimated time of impact of the Good Practice Medium impact – e.g. shortly beyond the pilot project period
Impact observed Better quality of life (societal). The practice was already shown to be feasible on a cohort of 200 insulin-treated patients with type 1 or type 2 diabetes, in which the expected outcomes have been largely achieved. Even though the practice has higher costs due to purchasing of the devices, software setting-up/customization and personnel recruitment (€750 per patient / year), it may translate into significantly lower costs due to savings from improved outcomes (better glucose control translates into fewer diabetes complications), appropriateness of SMBG performance and fewer hospitalizations (e.g., due to hypoglycaemia). This is particularly relevant considering that the practice is intended at the moment to be offered to insulin-treated patients with diabetes who are at high risk of hypoglycaemia. In the Apulian region during the period 2002-2010 - 385,527 subjects, 92% with type 2 diabetes, underwent 10,362 hospitalizations due to severe hypoglycaemia, with a total cost of € 31,256,985 (average cost per patient: € 3,016).
Transferability of the Good Practice Ready for transfer, but the innovative practice has not been transferred yet. The innovative practice has been developed on local/regional/national level and transferability has been considered and structural, political and systematic recommendations have been presented. However, the innovative practice has not been transferred yet. Meetings with local health authorities to assess interest in the new practice have been carried out, and industries producing glucometers have been involved. The results of the new practice have been presented in local, national and international meetings with specialized physicians and nurses. Meetings with patients' organisations are ongoing.

Part 5: Your organisation

Name of the organisation	Azienda Ospedaliero-Universitaria Policlinico Consorziale di Bari Universitò degli Studi di Bari Aldo Moro
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Type of organisation	Hospitals, Research centres, academia
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