Peter Beck

Design of a mobile, safety-critical in-hospital glucose management system

European Health Forum Gastein, 3rd October, 2013
Setting the scene: Diabetes Care

Primary Care

In-Hospital Care

Critically ill
Intensive Care (ICU)

Non-critically ill
General Ward
Glycaemic control in hospitals is not satisfactory...

... in England

- Diabetes patients on insulin had poor glucose control
- Medication errors are worryingly common and associated with poorer outcomes
- There is cause for concern about the care of inpatients with diabetes in most hospitals


... in Graz/Austria

Source: Neubauer et al. 2013
Motivation

- Glucose management is currently often regarded as secondary in clinical wards.
- Hyperglycaemia in hospital is an important marker for poor clinical outcome.
- Intensive treatment of diabetes/hyperglycaemia shows positive results concerning reduced mortality and morbidity rates and length of stay.
- Well established glucose management with close blood glucose control and appropriate medication is required.

J Clin Endocrinol Metab 97:16-38, 2012
Diabetes Care, 27, 2:553-591, 2004
Introduction of a Clinical Protocol is effective

- Basal-Bolus vs. Sliding Scale in inpatient management of patients with type 2 diabetes (RABBIT 2 Trial)
- BG target <140 mg/dl achieved in 66% of patients in basal-bolus group (•) and 38% in the sliding scale insulin (SSI) group (○)

(*P < 0.01; P < 0.05)

Umpierrez et al., Diabetes Care 30, 2007
Medication errors in hospitals are common, expensive, and sometimes harmful to patients.

Recommended by the Institute of Medicine as one way to reduce medication errors and patient harm.

Technical solutions to support process of ordering medications CPOE, CDSS and ePrescribing.

The evidence on these topics is only modest at best.

- Systems demonstrate improved practitioner performance (more optimal prescribing, reduction of medication errors) and improve patient surrogate outcomes.
- However, there is far less evidence on patient-level outcomes.
Compliance with European Medical Device Directive

- GlucoTab provides Clinical Decision Support
- **Classified as medical device** according to MDD
- Considered standards
  - IEC 62304 “Medical device software - Software life cycle processes”
  - ISO 14971 “Application of risk management to medical devices”
  - ISO 13485 “Quality management systems”
  - IEC 62366 “Application of usability engineering to medical devices”
  - EN 80001-1 “Application of risk management for IT-networks incorporating medical devices”
Clinical Workflow

- Bolus Insulin (Supplement)
- Bolus Insulin (Nutrition)
- Basal Insulin
- Insulin Total Daily Dose
- Blood Glucose Measurement
- Insulin Administration
- Physician Activity

- Morning: DSS
- Midday: DSS
- Evening: DSS
- Night: DSS
Main Features

- Provide glucose management directly at the point of care
- Documentation and visualization of relevant parameters
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- **Automated decision support** for insulin dosage
  (based on 3-4 BG measurements/day, SC insulin delivery)

- **Total Daily Dose** (physician directed)
Main Features

- Provide **glucose management** directly at the point of care.
- Documentation and visualization of relevant parameters.
- Automated decision support for insulin dosage (based on 3-4 BG measurements/day, subcutaneous insulin delivery).
- Total Daily Dose (physician-directed).
Main Features

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- **Workflow support** and reminder for **open tasks**
- **Sequence** of operation
- measurements as **prerequisite** for dose recommendation
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- Avoidance of manual/multiple data inputs (**HIS interfaces**)

- Time and location **independent access**
Development Methods

- Evolutionary development approach
- Interdisciplinary group
- Usability testing, user-centred design approach
- Mock-ups and early prototypes: triggers for clinical personnel
- Continuous risk management
GlucoTab Evolution
GlucoTab Evolution
GlucoTab Evolution
GlucoTab Evolution
GlucoTab Evolution
GlucoTab Evolution

Müller, Bernhard (61)
Room A-112, Bed 501
Admission Date: 01.12.2011

- **Basal/Bolus Regimen**
  - Bolus Insulin: NovoRapid
  - Basal Insulin: Lantus
  - Insulin Resistance: usual

**Blood Glucose Measurement**

**Insulin Administration**

**Daily Dose Adjustment**

**Glucose Profile**

- Blood Glucose Profile
  - show last 24h
  - show last 48h

**Administered Insulin**

- Bolus: 6, 16
- Basal: 4, 14
Conclusion

- End-users were involved in main decisions on functionality and design
- Use of triggers (mock-ups/prototypes)
  - end-users got a better idea of design possibilities/functionality
  - base for decisions and compromises between users
  - base for further development and/or changes
- Different points of view
  - Clinicians focus on key functionality, ease of use, workflow, integration
  - Technicians tend to gather as much functionality as possible
- User-centred approach is important to meet regulatory requirements
Discussion

- Even if computerized insulin orders are medically accurate, if systems are not built and designed well, they may fail in their purpose.
  - *Usability and user involvement were an important part of the GlucoTab development*
  - *BUT: Technical issues still could become barriers*

- Education as a key element of the introduction of a glucose management system is repeatedly mentioned in clinical studies
  - *Education is a factor of cost and effort*

- “Concern about causing hypoglycaemia” most important barrier to implementation of glycemic control programs
  - *Clinical studies will have to demonstrate good results*
Clinical Evaluation

- **analysis of glycaemic management**
- **REACTION - algorithm**
  - paper-based
- **tablet-based**
  - one ward
  - several wards

**Projects**

- ClinDiab01: Cardio, Endo
- ClinDiab02: Cardio, Endo
- ClinDiab03: Endo
- ClinDiab04: clinical wards, clinical wards
Efficacy, usability and sequence of operations of a workflow-integrated algorithm for basal-bolus insulin therapy in hospitalized type 2 diabetes patients

J. K. Mader1, T. K. Neubauer1, L. Schaupp1, T. Augustin2, P. Beck2, S. Spat2, B. Höll3, G. M. Treiber1, F. M. Fruhwald3, T. R. Plieker1, J. S. Plank1

1 Institute of Endocrinology and Metabolism, Department of Internal Medicine, Medical University of Graz, Graz, Austria
2 Institute of Geriatrics and Gerontology, Department of Internal Medicine, Medical University of Graz, Graz, Austria
3 Institute of Geriatrics and Gerontology, Department of Internal Medicine, Medical University of Graz, Graz, Austria
4 Department of Internal Medicine, Krankenhaus der Elisabethinen GmbH, Graz, Austria

Aims: To evaluate glycaemic control and usability of a workflow-integrated algorithm for basal-bolus insulin therapy in a proof-of-concept study to develop a decision support system in hospitalized patients with type 2 diabetes.

Methods: In this randomized study, 74 type 2 diabetes patients (24 females, age 68 ± 11 yrs, BMI 29 ± 2.4 kg/m² and body mass index 31 ± 8) were assigned to either algorithm-based treatment with a basal-bolus insulin therapy or to standard glycaemic management. Algorithm performance was assessed by continuous glucose monitoring and staff’s adherence to algorithm-calculated insulin dose.

Results: Average blood glucose levels (mmol/l) in the algorithm group were significantly reduced from 11.3 ± 3.8 (baseline) to 8.1 ± 3.8 (p < 0.001) over a period of 7.5 ± 4.6 days (p < 0.001). The algorithm group had a significantly higher percentage of glucose levels in the range 3.9 to 12.0 mmol/l compared with the standard group (33% vs. 23% and 73% vs. 53%, both p < 0.001). Physicians’ adherence to the algorithm-calculated basal-bolus insulin therapy was 95% and nurses’ adherence, to inject the algorithm-calculated insulin dose, was 95%. In the algorithm group, significantly more glucose values <3.9 mmol/l were found compared with the standard group (0.9% vs. 19%, p < 0.001). Significant fewer glucose levels >12.0 mmol/l were found in the algorithm group (5.6% vs. 18.4%, p < 0.05). Algorithm-guided management was more effective in establishing glycaemic control compared with standard management.

Conclusions: A workflow-integrated algorithm for basal-bolus insulin therapy is effective in establishing glycaemic control in hospitalized patients with type 2 diabetes and could be used in an electronic decision support system.

Keywords: Glycaemic control, insulin dosages, medical decision support systems.
Glycaemic control

- Open, single-centre controlled trial
  - Algorithm treatment, n=37 patients – Endocrinology department
  - Standard treatment, n=37 patients – Cardiology department
Nurses’ questionnaire

- Glucose control with algorithm is more efficient as compared to standard routine care?

- Do you think that the algorithm will help to prevent errors in the glycaemic management process?

- Did you feel confident using the algorithm based therapy?
Recommended glycaemic target could be achieved in 46% of the data with the REACTION algorithm.

No serious adverse events (i.e. severe hypo-hyper glycaemia).

Increased rate of mild hypoglycaemic events in the afternoon.

Paper-based REACTION algorithm has been very well accepted by staff.
Next Step

**analysis of glycaemic management**

**REACTION algorithm**

**tablet-based one ward**

**tablet-based several wards**

**tablet-based multicenter**

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**ClinDiab01**

**ClinDiab02**

**ClinDiab03**

**ClinDiab04**

**ClinDiab05**

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**Glucose**
Outlook

- Application outside the hospital
  - in nursing homes
  - mobile care at home
- Challenges
  - Full mobility
  - More independence of network connectivity
- Algorithm modification
  - Dose adjustments less frequently
  - More flexibility