Development, integration and operation of mobile, Android-based medical devices in hospitals: Experiences from the GlucoTab® system

**JOANNEUM RESEARCH**
HEALTH – Institute for Biomedicine and Health Sciences, Austria

**Medical University of Graz**
Division of Endocrinology and Metabolism, Austria

in cooperation with

**FORTH-ICS**
Institute of Computer Science, Foundation for Research and Technology, Greece

**Fraunhofer SIT**
Secure Information Technology, Germany

The REACTION project was partly funded by the European Commission under the 7th Framework Programme in the area of Personal Health Systems under Grant Agreement no. 248590
Agenda

- Introduction: Glycaemic control in hospital care
- The GlucoTab® System
  - System features
  - Mobile software as a Medical Device
  - Clinical trials (clinical validation)
- Hospital Infrastructure
  - Integration requirements
  - Integration scenarios
- Conclusion
Glycaemic control in hospital
Setting the scene: Diabetes Care

Primary Care

In-Hospital Care

Critically ill
Intensive Care (ICU)

Non-critically ill
General Ward
Prevalence of diabetes in hospitalized adult patients ranges between 6% and 26% in England.

Patients with diabetes have an increased length of hospital stay (8 versus 5 days).

The mean number of “good diabetes days” (BG-readings between 72-198 mg/dl) is 58% in England.

Room for improvement of diabetes treatment in hospitals!

NaDIA 2012
Recommandation for in-hospital BG management

„We recommend **insulin therapy** as the **preferred method** for achieving glycaemic control in hospitalized patients with hyperglycaemia.“  (Umpierrez et al. 2012)

„We recommend **clinical decision aids** at the point of care to guide prescribers in **implementing evidence-based guidelines.**”  (Draznin et al. 2013)
The GlucoTab® System
Features
Intended Use

- **Patients**
  
  Non critically-ill with *diabetes mellitus type 2* admitted at the *hospital ward*

- **Users**
  
  Healthcare professionals

- **System**
  
  - **Mobile** tablet-based client/server system
  - **Computerized Decision Support System (CDSS)**
  - Automated workflow support
  - Automated insulin dosing support (rule-based, open-loop)
Main Features

- Provide **glucose management** directly at the **point of care** (tablet with touch screen)

- **Automated decision support** for insulin dosage (based on 3-4 BG measurements a day, SC insulin delivery)
  - Total Daily Dose approved and ordered by physician
  - Individual insulin delivery approved and injected by nurse

- **Workflow support** and reminder for **open tasks**

- **Documentation** and **visualization** of the most important parameters (no data storage on the mobile device)

- **Time- and location-independent access**

- Avoidance of manual (and multiple) inputs; direct **connection to hospital information system**
GlucoTab architecture

- **GlucoTab System**
  - **Subsystem**: GlucoTab frontend
  - SOAP WS (Wi-Fi connection)
  - **Subsystem**: GlucoTab backend
  - use: HL7
    - SC_ID = "SC_IF01"
  - use: LDAP ActiveDirectory
    - SC_ID = "SC_IF02"
The GlucoTab® System
Clinical trials
Clinical validation
Course of Development

- **Pre-analysis**
  - Cardio
  - Endo
  - ClinDiab01

- **Paper-based**
  - Endo
  - ClinDiab02

- **Tablet-based**
  - GlucoTab®
  - 30 patients
  - Endo
  - ClinDiab03

- **Tablet-based**
  - GlucoTab®
  - 99 patients
  - Clinical wards
  - ClinDiab04

- **Tablet-based**
  - GlucoTab®
  - 50+ patients
  - Clinical wards
  - ClinDiab05
Clinical trials
Conclusion

- The GlucoTab System was constantly and continuously in use in clinical practice (20 months); till now approx. 180 patients treated with GlucoTab
- Average BG values of ~150 mg/dl (~190 mg/dl before)
- Risk of hypoglycaemia not increased compared to state-of-the-art clinical trials (1.8% < 70 mg/dl)
- High acceptance rates of user
- Performed insulin dose adjustments were small (<5%)
  → Therapy in line with clinical guidelines
- Substantially improved blood glucose control
  - Better than in recent best-practice studies
  - Superior to standard care
GlucoTab®
Medical Device Directive
CE certification
Compliance with amended European Medical Device Directive

- Software provides clinical decision support, and according to MDD it is **classified as medical device** (Class I)

- Considered standards
  - IEC 62304 “Medical device software - Software life cycle processes” -> manufacturer
  - ISO 14971 “Application of risk management to medical devices” -> manufacturer
  - ISO 13485 “Quality management systems” -> manufacturer
  - IEC 62366 “Application of usability engineering to medical devices” -> manufacturer
  - EN 80001-1 “Application of risk management for IT-networks incorporating medical devices” -> hospital-IT operator
**Work effort**

- **ISO 13485** already established at our institute (quality management system for medical devices)

- **New: IEC 62304, IEC 62366** for medical software development newly implemented and integrated into ISO 13485 → ~10 SOP, ~40 (living) documents

- TÜV certification necessary (yearly audits)

- Work effort implement into ISO 13485: 30 person months

- **Improved work effort to run system** due to documentation overhead (~1/3)
The GlucoTab® System
Declaration of conformity
Approval as a medical device since 15.11.2013
Hospital Infrastructure
Integration requirements
Hospital infrastructure

- Wi-Fi support in hospital\(^1\): US 91%, ES 85%, DE 57%, IT 32%
- Healthcare tablet – fasted growing mobile segment in next years (US)\(^1\)

<table>
<thead>
<tr>
<th>Mobile Technology</th>
<th>Current situation (%)</th>
<th>Target situation (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laptop computers</td>
<td>87</td>
<td>15</td>
</tr>
<tr>
<td>Computers/ workstations on wheel</td>
<td>81</td>
<td>14</td>
</tr>
<tr>
<td>Smart-phones</td>
<td>69</td>
<td>30</td>
</tr>
<tr>
<td>Pagers</td>
<td>67</td>
<td>8</td>
</tr>
<tr>
<td>Cellular Phones</td>
<td>56</td>
<td>14</td>
</tr>
<tr>
<td>Tablet computers NOT designed for healthcare</td>
<td>44</td>
<td>49</td>
</tr>
<tr>
<td>Tablet computers designed for healthcare</td>
<td>43</td>
<td>63</td>
</tr>
</tbody>
</table>

\(^1\)Questionnaire of Healthcare Information and Management Systems Society (HIMMS) to Hospital IT managers 2013
GlucoTab integration requirements

Example: 2 tablets at each ward – medium sized hospital IT-operator → 50 tablets to maintain → challenge in terms of integration, operation and maintenance

Main requirements

- Domain Integration
- Software Inventory and Distribution
- User Management and Access Authorization
- Remote Maintenance

→ best solution: Mobile Device Management System (MDMS)
Usage scenarios: MDMS

**MDMS Scenarios**

- **(1) MDMS is directly hosted in the hospital by the hospital-IT operator**
  + part of hospital-IT; no effort for manufacturer
  - not feasible if GlucoTab® is only mobile device at hospital

- **(2) manufacturer runs the MDMS for the GlucoTab® frontend devices**
  + no additional effort for hospital-IT operator
  - effort for manufacturer

- **(3) GlucoTab® backend provides reduced MDMS functionality**
  + no need for MDMS
  - increased effort for manufacturer
Hospital Infrastructure
Integration scenarios
Integration scenarios I

**Basic Integration**

- (1) GlucoTab® backend on hospital server
- (2) HL7 interface for automated patient management
- (3) Hospital Wi-Fi connecting the GlucoTab® frontend Tablet

**Extended Integration**

- (4) active directory interface for hospital user management
- (5) HL7 interface for automated medical parameter transfer (e.g. blood glucose, creatinine)

**Deep Integration I**

- (6a) GlucoTab connected with CPOE system and software fever chart of EMR via HL7
Integration scenarios II

- **Deep Integration II**
  - (6b) GlucoTab® functionality directly implemented in EMR (EMR has to be a medical device?)

- **No Integration**
  - technical prerequisites like Wi-Fi is not available
  - (I) Hosting of the GlucoTab® server outside the hospital
  - (II) connection GlucoTab® server and Tab-clients using GSM
  - (III) use of the already developed standalone user management (Fraunhofer)
  - (IV) manual management of patient transfers (UI)
  - (V) manual entry of medical parameters like blood glucose values
mobile devices (in hospitals) like **smartphones or tablets used as medical devices** offer …

- **Various advantages**
  - time- and location independent access to information
  - easy to carry
  - high usability, higher acceptance
  - decision and clinical workflow support directly at patient bed
  - …

- **Pose challenges for manufacturer and hospital-IT**
  - High effort for development (software as medical device, QM system)
  - High effort for evaluation/validation (clinical trials)
  - Complex integration scenarios
  - Additional tooling for operation and maintenance (i.e. MDMS)
  - …
Thank you for your attention

JOANNEUM RESEARCH
Forschungsgesellschaft mbH
HEALTH – Institute for Biomedicine and Health Sciences
Neue Stiftungtalstraße 2, 8010 Graz
+43 316 876-4106
stephan.spat@joanneum.at
www.joanneum.at/health