
Patient Monitoring and Informatics

New Opportunities for the Next Decade

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Patient Monitoring and Informatics

New Opportunities

- Common Sense Approach
- Introduction into Patient Monitoring and Informatics
- Requirements from a changing healthcare environment
- Case study: Tight Glycemic Control
- Challenges and Opportunities



Patient Monitoring and Informatics

New Opportunities

Common Sense Approach

- Is there clinical need?
- Is there clinical benefit?
- Is there acceptance in the medical community?
- Is there financial benefit for the user?
- Where is the market?



Patient Monitoring and Informatics Definitions

Informatics

- Medical Informatics can be defined as any application of information management technology in healthcare [Imhoff M et al, *Intensive Care Med* 2000]

Monitoring

- Measurement of a parameter of a system (human being, aircraft, etc.)
- Continuous or semi-continuous measurement
- Automatic function over extended time periods (w/o user interaction)
- Warning capability – alarms
- Display of changes over time (e.g. trends)
- Timeliness of measurements in the clinical context
- No direct therapeutic effect



Benefits from Patient Monitoring

- Clinical benefit seems intuitive, but ...
 - Benefit could not be found
 - Pulmonary artery catheter [Connors et al, JAMA 1996]
 - Pulse oximetry [Pedersen et al, Cochr Review 2003]
 - Benefit could be found
 - ScvO2 / early goal directed therapy in sepsis [Rivers et al, NEJM 2001]
 - Cardiac output / perioperative hemodynamic optimization [Boyd, JAMA 1993]
 - Benefit depends on the translation of monitoring into therapy
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- ➔ Process Control
 - ➔ Decision Support
 - ➔ Application of Informatics







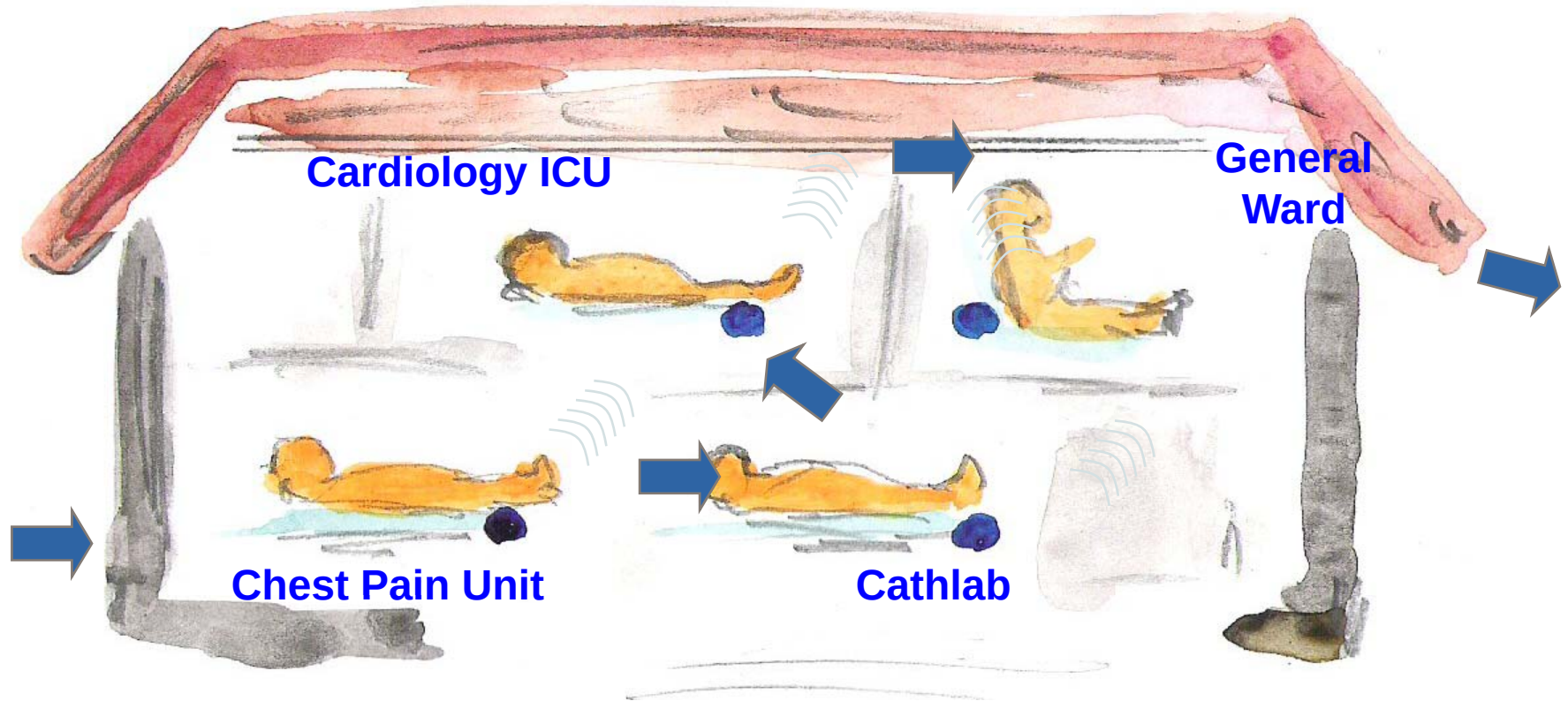
Changes in Hospital Care

- Increasing acuity
- Decreasing length of stay
- Increasing patient safety concerns
- Increasing liability challenges
- Shortage of ICU beds
- Shortage of qualified staff
- Implementation of intermediate care
- Telemetry units
- Critical care outreach (CCOT, MET, RRT, ...)
- Monitoring in general wards
- Improving informatics infrastructures



Continuum of Care

Continuous Monitoring



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Monitoring in the Hospital

“Traditional” Monitoring (ICU/OR)

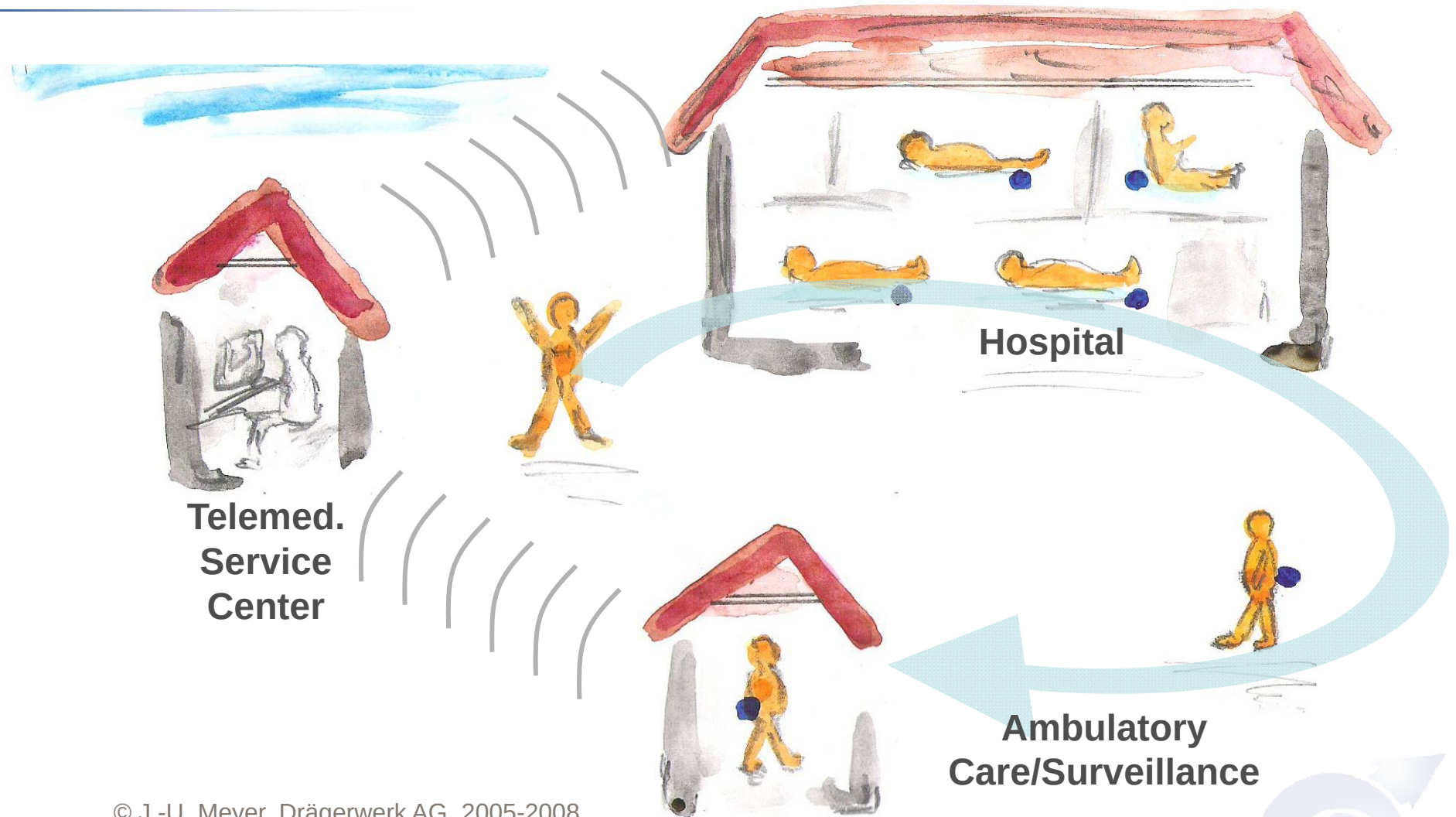
- Immobile patients
- Invasive monitoring
- Cables and lines are “acceptable”
- Patient comfort not a primary concern
- High risk of immediately life-threatening changes
- High nurse/patient ratio
- Caregiver presence

“Extended” Monitoring (outside ICU/OR)

- Potentially mobile patients
- Non-invasive monitoring
- Cables and lines are not acceptable
- Patient comfort highly relevant
- Less risk of immediately life-threatening changes
- Low nurse/patient ratio
- Limited caregiver presence



Continuum of Care Continuous Monitoring



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Monitoring Outside the Hospital

- Mobile, active patients
- Monitoring during activities of daily living
 - non-invasive, non-obtrusive, no cables, ...
 - patient comfort!
- Easy handling, application and operation without help
- No caregiver presence
- Alarms cannot be answered immediately!
- Early warning, before a situation becomes life-threatening
- ➔ Monitoring devices and sensors
- ➔ Data communication and analysis
- ➔ Remote services and patient support



Tight Glycemic Control

- Tight Glycemic Control (TGC)
 - *TGC in intensive care:*
Maintenance of blood glucose levels 80-110 mg/dl (4.4-6.1 mmol/l) with IV Insulin infusions (and IV glucose infusions)
 - *TGC (intensive insulin therapy) in diabetes care:*
Frequent insulin injection (>3/d or continuous) and frequent blood glucose measurements
 - ➔ Integration of Patient Monitoring and Informatics
- Management of Diabetes mellitus type 1 and type 2
 - better long-term outcomes (complications, survival)
 - significant DM type 1 populations (0.2-0.5%/pop., constant)
 - huge DM type 2 populations (4-8%/pop., increasing)
- Intensive Care Medicine
 - improved outcomes (survival, organ failure)
 - “low cost” intervention
- ➔ Opportunities for new technologies
- ➔ Significant perceived market potential



Tight Glycemic Control

New Opportunities

Common Sense Approach

- Is there clinical need?
 - TGC without monitoring and decision support is barely feasible
- Is there clinical benefit?
 - Clinical studies
- Is there acceptance in the medical community?
 - Guidelines, best practice
- Is there financial benefit?
 - What is the cost of current practice?
 - What is the cost of the new technology?
- Where is the market?



Hyperglycemia and In-Patient Outcomes

- Hyperglycemia is associated with increased hospital mortality
 - Surgical and non-surgical patients
 - Especially in patients without prior diabetes
- Numerous studies and reviews
 - Capes SE, et al.; Stroke 2001
 - Systematic review of 32 studies
 - Acute hyperglycemia is associated with increased mortality after stroke.
 - Umpierrez GE, et al.; J Clin Endocrinol Metab 2002
 - Observational study with 2,030 patients
 - Hyperglycemia is an independent marker of in-hospital mortality
 - Krinsley JS, et al; Mayo Clin Proc 2003
 - Observational study with 1,826 patients
 - Hyperglycemia is associated with hospital mortality.
- ***Does control of hyperglycemia change outcomes?***



TGC Studies, Leuven I

van den Berghe G, et al.; NEJM 2001

- Seminal study into glucose control
 - Prospective randomized controlled trial
 - 1548 patients (mostly post cardiac surgery)
 - maintenance of blood glucose in normal range (80-110 mg/dl)
- Results
 - Significant reduction of mortality, complications, and cost
 - But only in patients with ICU LOS > 5 d
 - No differences in patients with shorter LOS.
 - Only surgical/open heart patients, no projections to medical patients



Tight Glycemic Control Best Practice Guidelines

- No “official” guidelines but several strong recommendations
 - Surviving Sepsis Campaign (SSC) Sepsis Bundles
 - Institute of Healthcare Improvement (IHI)
 - Volunteer Hospital Association
 - Many intensivists want to implement TGC, but
 - Target glucose levels: 80-110 mg/dl?
 - Which patient groups?
 - Glucose measurements intervals 1-4 hours (or less?)
- ➔ Significant hype about TGC



Tight Glycemic Control

The Challenges and Opportunities

- **Monitoring of blood glucose levels**
- **Administration of insulin and glucose**
- **Decision support for dosing and titration**



Glucose Monitoring

Current State of the Art

- Manual arterial/venous blood sampling
 - Central lab
 - Stat lab in the ICU (near POC)
 - Test strip (at POC)
- Manual capillary blood sampling
 - (Central lab)
 - Stat lab in the ICU (near POC)
 - Test strip (at POC)
- Finger prick
 - Test strip (at POC)



Glucose Monitoring Clinical Requirements

Glucose Monitoring Technologies can enable TGC

Requirements for ICU Glucose Monitoring (unproven!)

- Automatic
- Fast: less than 2 min measurement time
- Short intervals: 10 min or less
- High precision: higher precision than for ambulatory diabetes control
- Invasiveness: Invasive – Minimally invasive – Non-invasive?

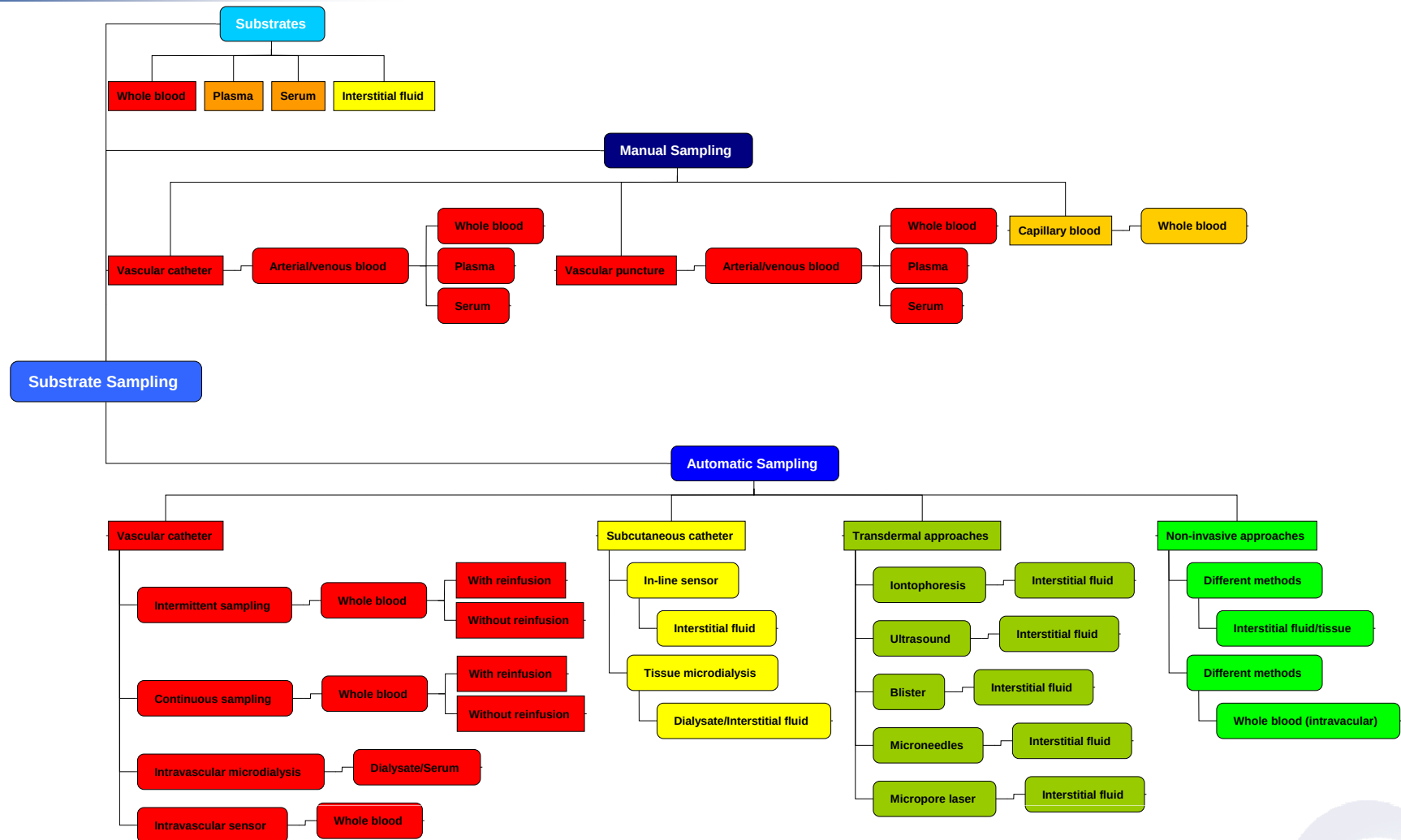
Two challenges

- Substrate sampling
- Blood glucose measurement



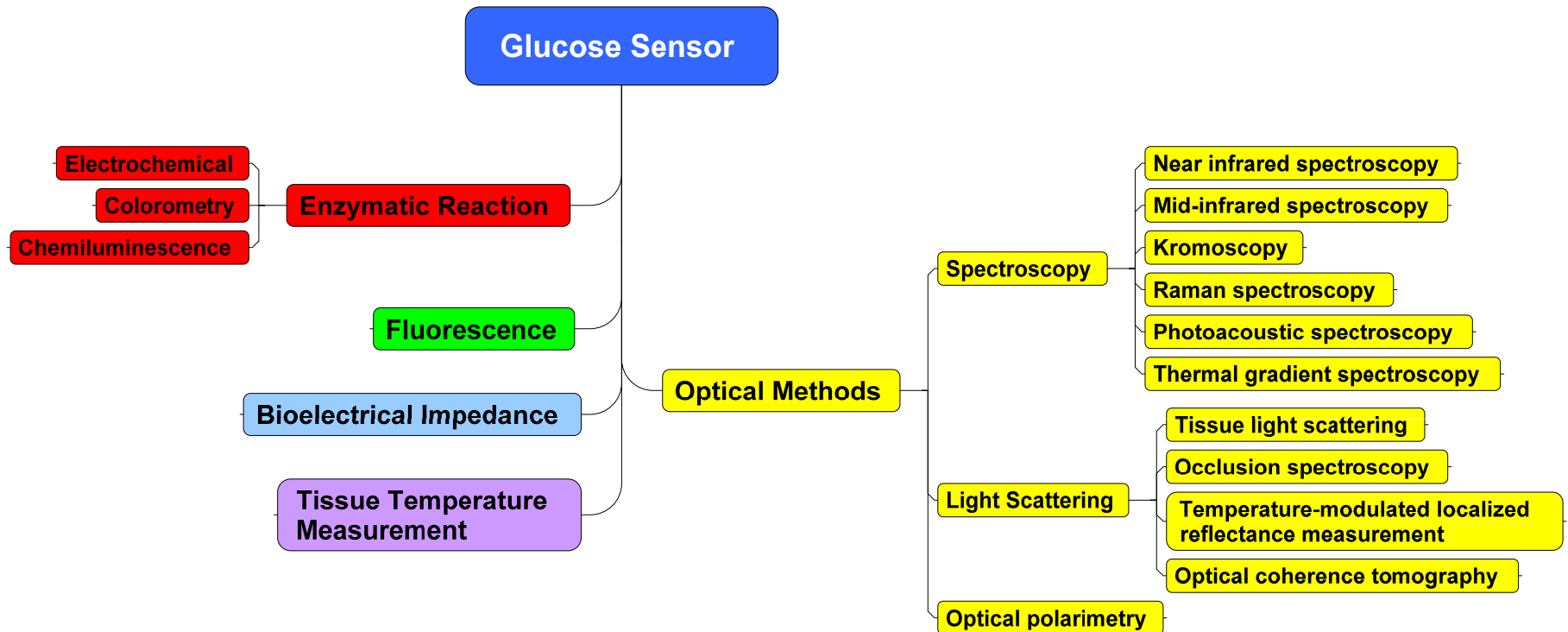
Continuous Glucose Monitoring Technologies

Substrate Sampling



Continuous Glucose Monitoring Technologies

Sensor Technologies



Tight Glycemic Control

Administration of Insulin and Glucose

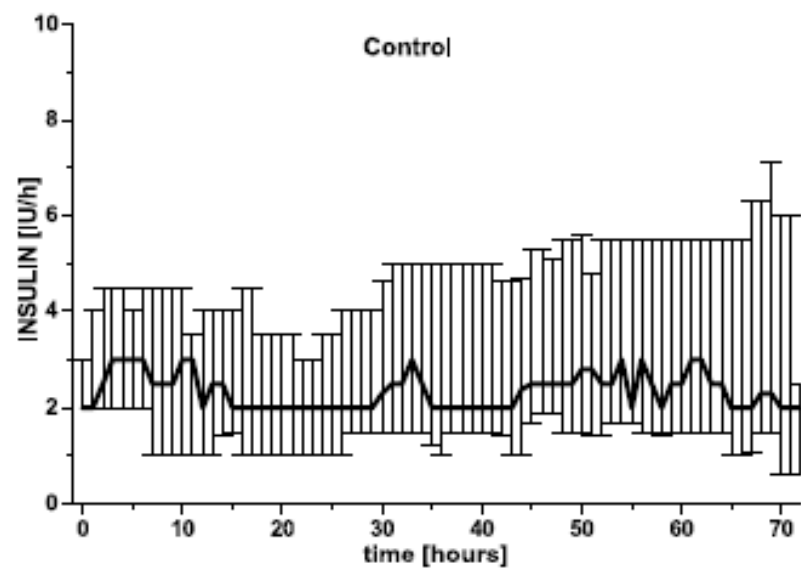
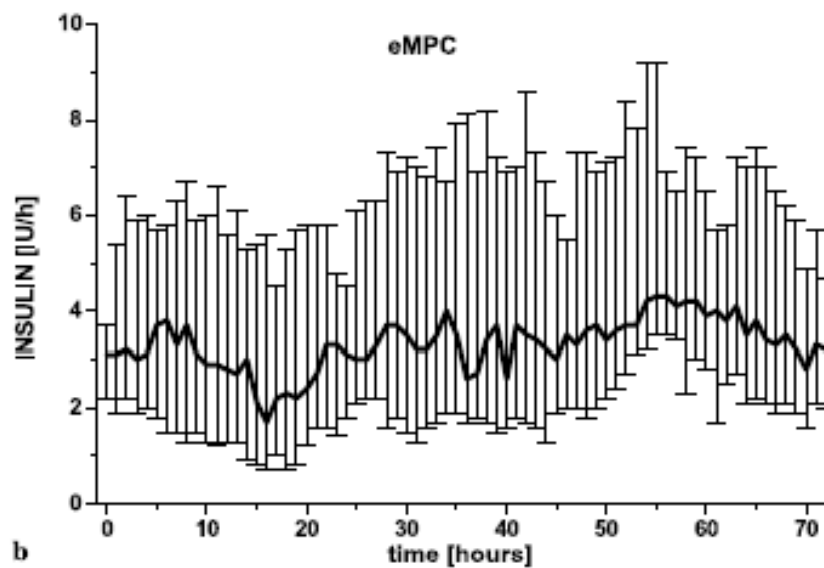
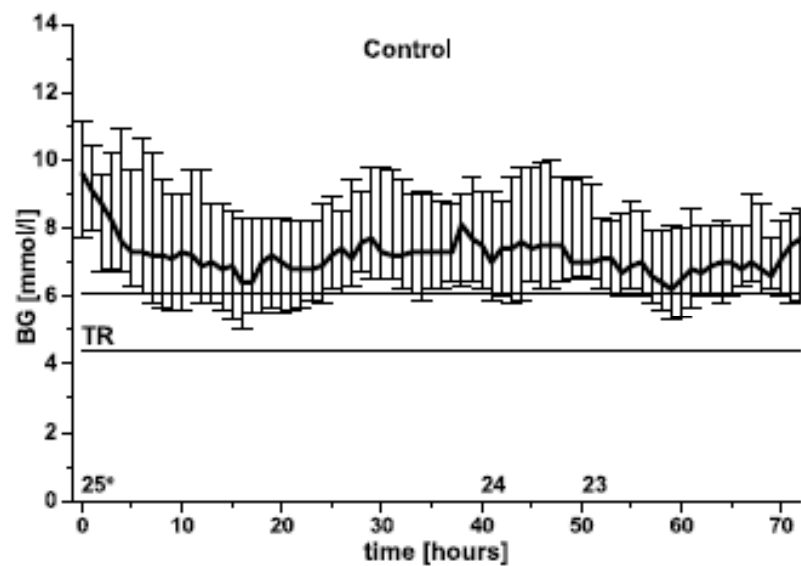
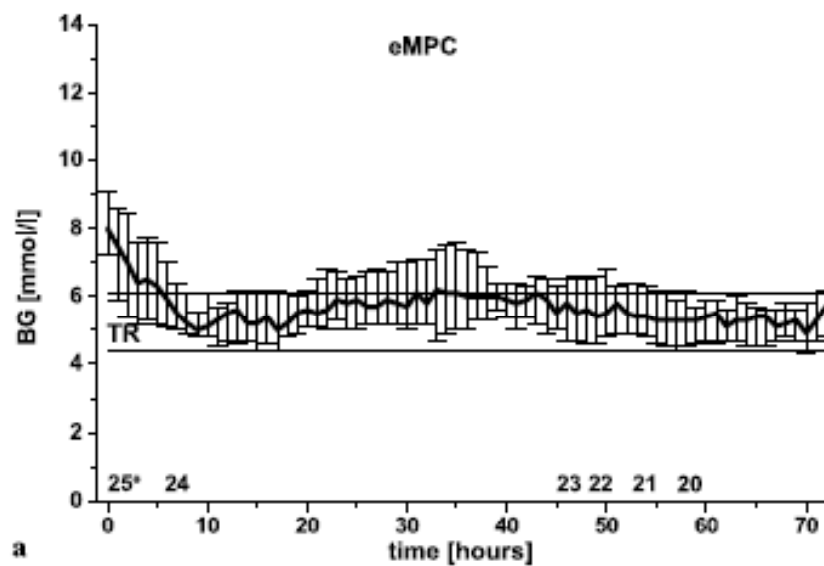
- Standard infusion systems and syringe pumps
 - Manual control
 - Bi-directional interfaces to computer systems (CPOE, CDSS)
- Pumps/pump controllers may serve as computer platform for DSS algorithms



Tight Glycemic Control Decision Support

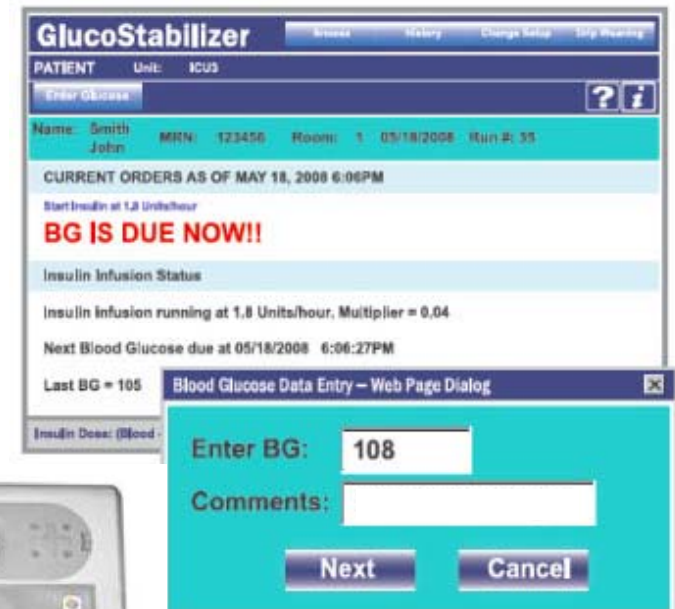
- TGC algorithms for clinical care
 - Several protocols tested in clinical studies
- TGC decision support software
 - Systems for clinical studies
 - Commercial PC-based solutions
 - Integration into CPOE/HCIS/CDSS
- Closed-loop control = Holy Grail





Tight Glycemic Control Commercial Decision Support Tools

- MD Scientific, LLC
 - Endotool Glucose Management System
 - www.mdscientific.com
 - Acquired by Hospira 10/2009
- MDN Medical Decisions Network
 - GlucoStabilizer
 - www.mdnoutcomes.net
- GlucoTec, Inc.
 - G+™ Model 2020
 - Tablet PC based solution
 - G+™ Analytics
 - posthoc analysis software
 - www.glucotec.com
- Clinical utility?
- Cost effectiveness?
- Integration with CIS/EMR?



**ICU
Patient**



1. Glucose Measurement

Manual Blood Sampling
Bedside Glucose Meter



**Physician /
Nurse**

2. CLINICIP system

Enter glucose level
Confirm insulin infusion
Await next sample reminder



Market Potential

Acceptable Cost for Glucose Monitoring

- Assumptions
 - Blood gas analyzer on ICU
 - 4-8 blood gas analyses required per day
 - Glucose protocol requires measurement q1h (24 measurements/d)
 - Blood sampling takes 5 minutes nursing time (= 120 min/patient; 30€/h)
 - Blood gas disposables/reagents ~1€ (glucose test strip ~0.30-0.50€)
- Total cost for glucose monitoring with blood gas analyzer
 - 24 € disposables
 - 60 € working time
 - minus 8 blood gas measurements
 - 8€ disposables
 - 20€ working time
- Effective cost of glucose monitoring: 56€/d
- A new monitoring technology should not be much more expensive



Market Potential

TGC in Intensive Care

- Worldwide 10+M ICU admissions per year
- Surgical critical care
 - 10-50% of all ICU patients
- Non-surgical critical care ??
- Pediatric critical care ??
- 1M patients eligible for TGC/year (mean ICU LOS 3 days)
 - US\$200 over 3 days
 - US\$200M per year worldwide
- Global high-acuity monitoring market: US\$2-3B
- Global glucose test strip market: > US\$10B



TGC Studies, Leuven II

van den Berghe, et al., NEJM 2006

- Continuation of 2001 study in non-surgical patients
 - Prospective randomized controlled trial: 1200 patients
 - mixed medical ICU patients in a tertiary referral center
 - maintenance of blood glucose in normal range (80-110 mg/dl)
 - Results
 - Overall mortality unchanged
 - Reduced mortality in patients with ICU LOS > 3 d
 - **Increased mortality in patients with ICU LOS < 3 d!**
- ➔ Case for TGC is not as clear as often thought
- ➔ More studies needed



TGC Studies, VISEP, Glucontrol, NICE-SUGAR

- VISEP study
 - TGC arm stopped after 488 patients
 - Hypoglycemia 12.1% vs. 2.1%
 - No differences in mortality or complications
- Glucontrol (<http://clinicaltrials.gov/show/NCT00107601>)
 - Stopped at interim analysis (05/2006) after 1,101 patients (3,500 planned)
 - High rate of hypoglycemia in TGC group (8.6% vs. 2.4%)
 - No difference in mortality
- NICE-SUGAR (<http://www.clinicaltrials.gov/ct/show/NCT00220987>)
 - 95% patient enrolment (of 6,100 patients)



Tight Glycemic Control

Where is the Market?

- Patient populations for TGC not sufficiently defined
 - Market size remains unclear
- Contradicting study results
 - Market acceptance may take much longer (if any!)
- Therapeutic ranges?
- Complications and side effects?
- Compliance with guidelines [*Brunkhorst et al, Crit Care Med 2008*]
 - TGC: 66% perceived compliance vs. 6% actual compliance
- ***The hype may be over!***



Tight Glycemic Control

Large MedTech Vendors

- Are they active in this area?
 - Is the market large enough?
 - Does a new technology match the current/future portfolios?
 - Can it be sold through the existing sales organizations?
 - Can it be harmful to their current businesses?
 - Is the business model suitable?
 - Electromedical/imaging companies expand into biochemical diagnostics
- Philips
 - Own biochemical developments (lab on a chip)
 - Integration of monitoring & IT
 - Cooperation preferred with “brand names”
 - Siemens
 - Acquisition of 3 lab companies
 - World leader in central labs and blood gas analyzers
 - Strong integration of imaging, biochemical diagnostics and informatics



Large MedTech Vendors

New Opportunities

How do large companies look at new market trends/opportunities?

- Excellent knowledge of their markets and their customers
- Significant expertise in marketing, sales, R&D, production
- They tend to be conservative and slow
- But large vendors may also try to expand into new markets
 - hospital monitoring → home monitoring
 - electromedical technologies → biochemical technologies
 - hospital beds → in-patient monitoring
 - These may be great opportunities for start-ups
- New players enter the medical market



Patient Monitoring and Informatics

New Opportunities

Traditional high-acuity monitoring?

Inpatient monitoring outside high-acuity settings!

Monitoring outside the hospital!

- Wearable devices (spot-checking, self-testing, continuous monitoring)
- Implants
 - Monitoring of the patient
 - Monitoring of the implant
- Sensors – new sensor technologies, new biosignal/data analysis
- Energy supply and management
- User interfaces
- Communications, networks
- Decision support, data management and analysis
- Patient-centered services



Thank You

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