Implementing Glucose Control in 2009 and Beyond: Changes in Patterns and Perceptions

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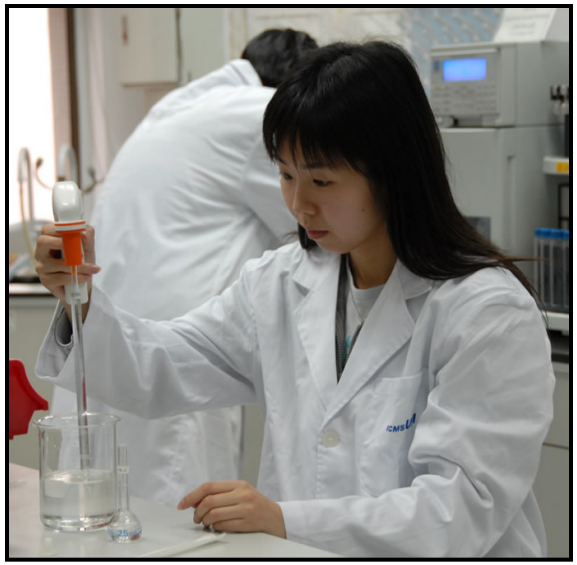
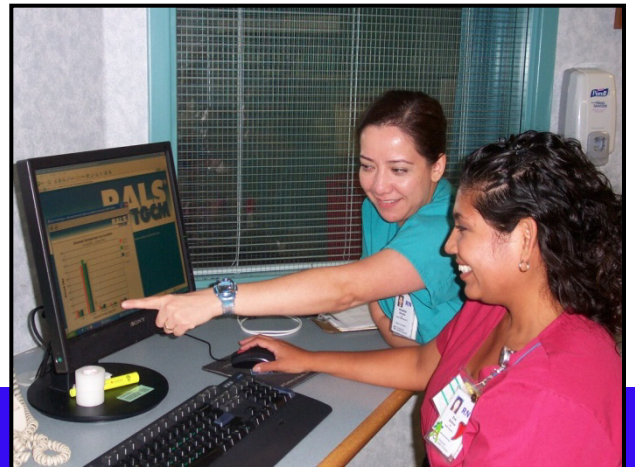
Relationships



Improving
Collaboration
And Outcomes



Background

Why we started controlling glucose in the STICU

- **Hyperglycemia:**
  - Pre-existing Diabetes
  - Medications
  - Nutrition
  - Surgery
  - Dialysis Solutions
  - Hypothermia
  - Anesthesia
  - Stress Induced Hyperglycemia

Benefits of TGC

- Patient:
  - Sepsis
  - Wound Infection
  - Dialysis
  - Blood Transfusions
  - Polyneuropathy
  - Ischemic Brain Injury
  - Respiratory Failure
  - Pneumonia
  - Infarct Size of AMI & Stroke

So Were is Glucose control Going in 2009 ?

Greet Van den Berghe 2001

- Prospective RCT -Surgical ICU patients
- Blood glucose level 80-110 or 180-200
- 1548 patients
- IIT 32% reduction in mortality
- IIT reduced sepsis by 46%
- IIT reduced LOS

N Engl J med 2006;354: 449-61

Greet Van den Berghe 2006

- Prospective RCT – Medical ICU
- Blood glucose level 80-110 or 180-200
- 1200 patients
- ICU LOS < 3days – decreased morbidity, no reduction in mortality
- ICU LOS >3 day decrease in morbidity and mortality

N Engl J med 2006;354: 449-61

Hyperglycemia & Strokes 2006

- Hyperglycemia after SAH (Prospective study of 281 patients)
  - Increased complications
  - Increased LOS
  - Increased death & disability
- Hyperglycemia after Acute Ischemic Stroke (retrospective 960 patients)
  - Increased mortality

Stroke.2006;37:199-203
ACAD EMERG MED 2006; 13:174-180

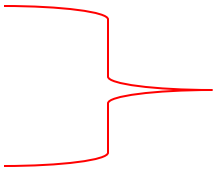
AHA Scientific Statement 2008

- Hyperglycemia in ACS patients, gaps in knowledge:
  - Appropriate blood glucose level
  - Appropriate method for measuring and monitoring
  - Benefits

Circulation. 2008;117:1610-1619

AHA Scientific Statement 2008

- Hyperglycemia
  - Detrimental to ischemic myocardium
    - Perfusion defects related to micro vascular dysfunction
    - Lower rates of spontaneous reperfusion
    - Endothelial dysfunction
    - Increased platelet aggregation
    - Increased markers of vascular inflammation
    - Increased fatty acid concentration
    - Insulin resistance
    - Impaired myocardium glucose utilization



Increased O2 consumption

Circulation. 2008;117:1610-1619

AHA Scientific Statement 2008

- Recommendations
  - Initial lab work to include glucose levels
  - Blood glucose monitoring of ACS patients admitted to ICU
    - Goal 90-140
  - IV insulin infusion most effective for control of glucose in ICU
  - Treatment started as early as possible
  - Non-ICU setting BG goal <180

Circulation. 2008;117:1610-1619

The Glucontrol study 2009

- Prospective RCT of 1078 patients
  - 21 Medical/Surgical ICUs
- Study stopped due to protocol violation

Intensive Care Med July 2009

The Glucontrol Study 2009

Intensive Therapy

- Target BG 4.4-6.1 mmol/L
- Achieved 6.5 (5.5-6.8)
- Mortality 17.2%
- Hypoglycemia 8.7%

Conventional Therapy

- Target 7.8-10mmol/L
- Achieved 8.0 (7.1-9.0)
- Mortality 15.3%
- Hypoglycemia 2.7%

•Study under powered for any statistical significance

Intensive Care Med July 2009

Differences in Glucontrol Versus other studies

- Caloric intake
- Hypoglycemia
- Case mix and severity of illness
- Method of BG measurement

NICE Sugar Study

- Enrolled 6104 patients in RCT in Medical & Surgical ICUs, 42 hospital (Australia, New Zealand, and Canada) 87.5% were from Australia & New Zealand
  - 3054 Intensive
  - 3050 Conventional
- Criteria minimum 3 days ICU
- Targets 81-108 mg/dL or >180 mg/dL
- 90 day outcomes measures

N ENGL J MED 2009; 360: 1283-97

NICE Sugar Study Findings

Intensive Insulin

- 3016 patients
- Insulin 50.2 +/- 38.1
- Mean tw BG 115 +/-18 mg/dL
- 27.5% mortality
- Hypoglycemia 6.8%

Conventional

- 3014 patients
- Insulin 16.9 +/- 29.0
- Mean tw BG 144 +/-23 mg/dL
- 24.9% mortality
- Hypoglycemia 0.5%

N ENGL J MED 2009; 360: 1283-97

Differences in findings NICE versus others

- Increased cardiovascular death
- No difference in multiple organ failure
- No difference in LOS
- No difference in Vent days
- No difference in operative vs nonoperative
- No difference in diabetic vs nondiabetic
- Blood samples
- Caloric intake

N ENGL J MED 2009; 360: 1283-97

Joint Statement from ADA & AACE on the NICE SUGAR Study March 24, 2009

- Findings from the NICE SUGAR Study should not lead to the abandonment of the concept of good management in the hospital setting
- Strategies must be identified to help establish structured protocols for safe and effective management of blood glucose in the ICU and on the wards

Joint Statement from AACE & ADA on Inpatient Glycemic Control May 8, 2009

- Revised glucose targets:
  - 140-180 mg/dL ICU
  - 100-180 mg/dL general wards
- Multidisciplinary approach from admission to discharge

Meta-analysis including NICE-SUGAR 2009

- 26 trials included
- 13,567 patients
- Findings:
  - No difference in mortality between groups
  - Risk of hypoglycemia did not differ by type of ICU or intensity of therapy
  - Effect of IIT differed by ICU setting
  - Cannot exclude the possibility that some patients may benefit from IIT

CMAJ 2009; 180(8):821-827

Glycemic Control & Diabetes Mellitus After Total Joint Arthroplasty 2009

- Retrospective Study – Patients undergoing joint surgery
  - Compared controlled diabetes, uncontrolled diabetes, no diabetes in over million patients
- Uncontrolled diabetes
  - Increased complications
  - Increased mortality
  - Increased LOS

J Bone Joint Surg Am. 2009;91:1621-9

Hyperglycemia and Critical Illness Neuromyopathy (CINM) 2009

- Hypothesis: Axonal injury caused by
  - Microcircular dysfunction -> impaired O2 and nutrition (sepsis/hyperglycemia)
  - Cytokine induced changes in microvascular permeability ->edema->hypoxia and energy depletion
  - Increased uptake of glucose -> enhanced reactive oxygen species-> mitochondrial dysfuntion
- Examined 2 large RCT for IIT
  - IIT was associated with decrease in CINM

AACN Advanced Critical Care 2009, 20(3) :243-253

AACE & ADA Consensus Statement on Inpatient Glycemic Control 2009

- Does glycemic control improve outcomes?
- What glycemic targets can be recommended?
- What treatment options are available for achieving optimal glycemic target?
- Is inpatient management of hyperglycemia safe?
- What systems need to be in place to achieve these recommendations?
- Is treatment of inpatient hyperglycemia cost-effective?
- What are the strategies for transitioning to OP care?

Lets answer these

Questions

Glycemic Control Management

- **Process/Implementation Management**
  - Support, multidisciplinary team, assessment of current practice, barriers, & education
- **Medication Management**
  - Protocols, order sets & Insulin (Drips, S/S, Basal)
- **Data Management**
  - Results

ACE/ADA Consensus Statement, Endocrine Practice.2009:15(4):1-13

Process Management

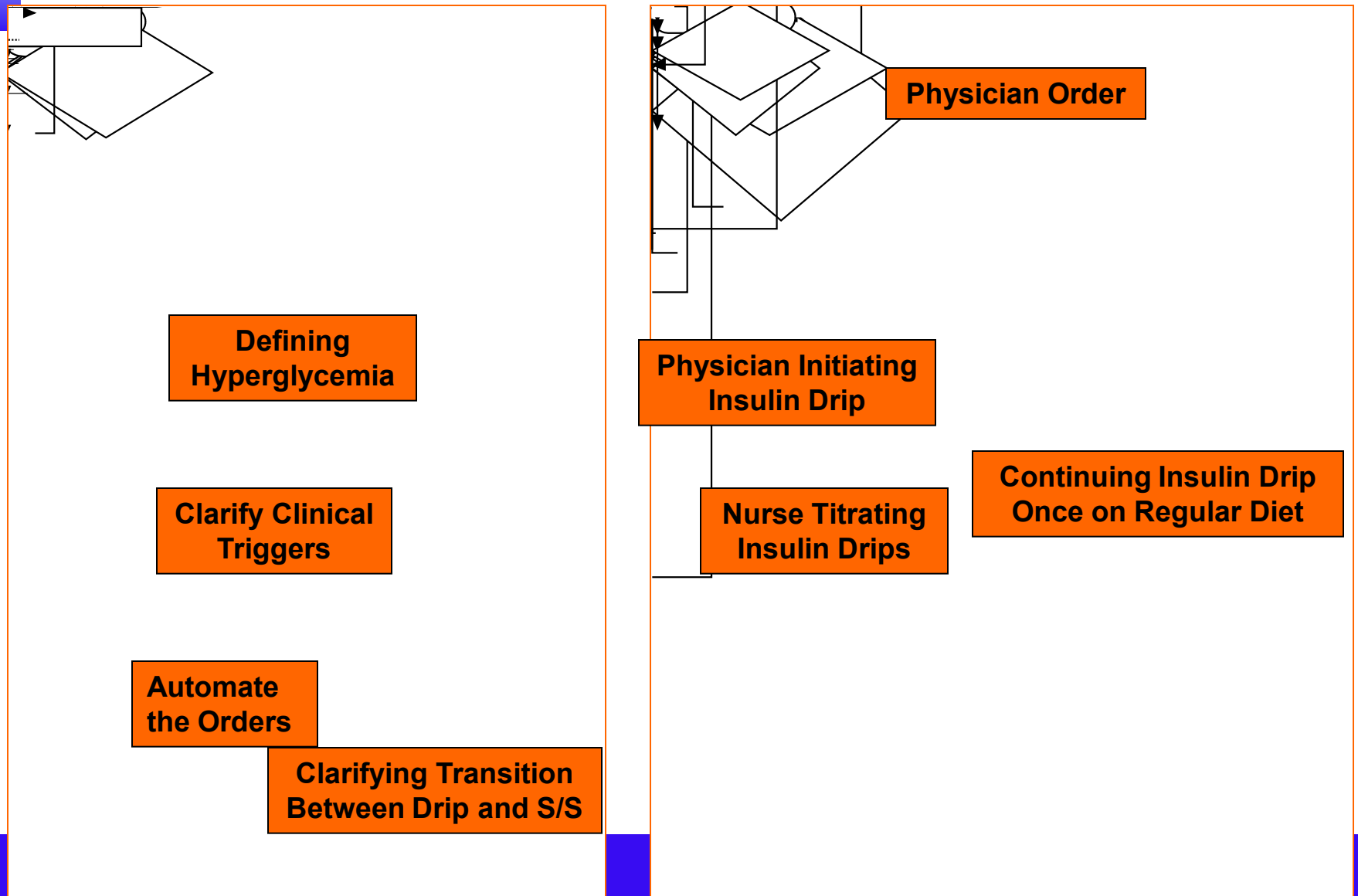
- Support:
  - Administration
  - Physician
  - Nursing
  - Laboratory
  - Pharmacy
  - Dietary
  - Case management
  - Information Systems
  - Quality Dept.

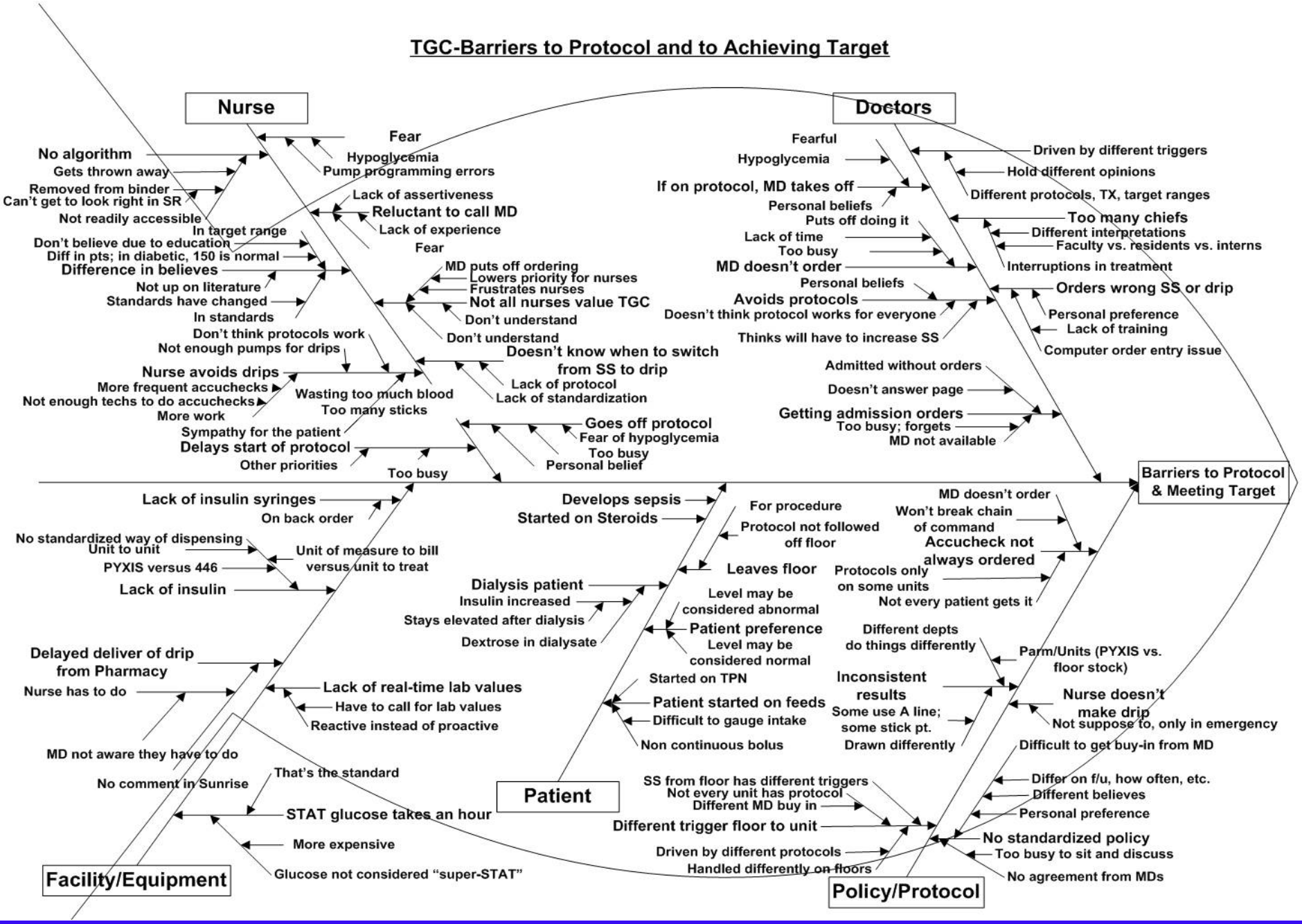
[1]ACE/ADA Consensus Statement, Endocrine Practice.2009:15(4):1-17

Process Management

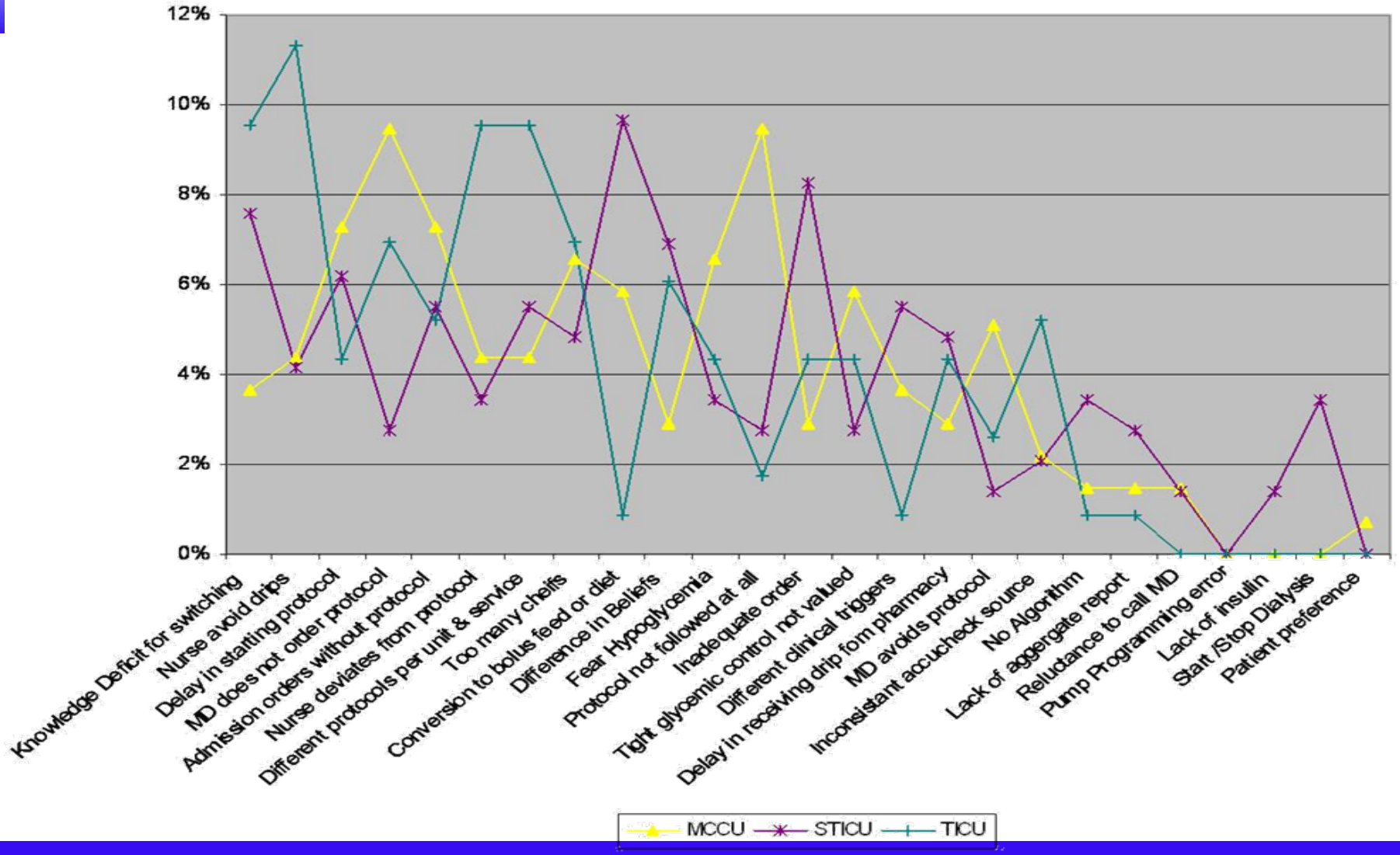
- Inpatient Hyperglycemia
  - **Stress Hyperglycemia (Temporary)**
    - Resolves, no further action needed
  - **Previously Undiagnosed Diabetes**
    - Need to confirm
    - Implement therapy & Education
    - Outpatient follow-up
  - **Previously Diagnosed Diabetes**
    - Evaluate level of control and compliance
    - Adjust therapy if necessary
    - Assess for complications
    - Outpatient follow-up

Assessing Current Practice



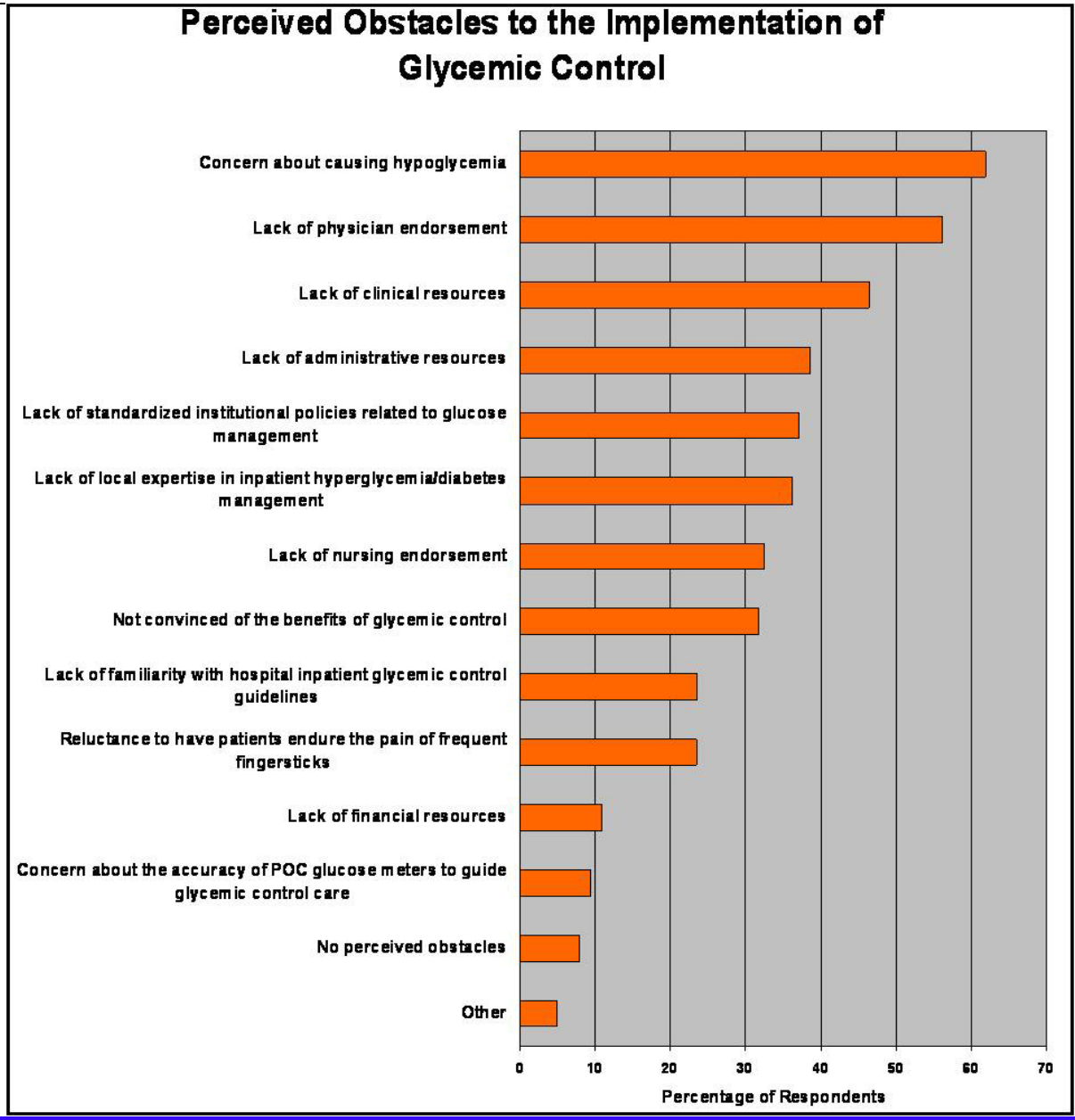

TGC-Barriers to Protocol and to Achieving Target
Nurse
Doctors
Barriers to Protocol & Meeting Target
Patient
Facility/Equipment
Policy/Protocol
Fear
Hypoglycemia
Pump programming errors
No algorithm
Gets thrown away
Removed from binder
Can't get to look right in SR
Not readily accessible
Lack of assertiveness
Reluctant to call MD
Lack of experience
In target range
Don't believe due to education
Diff in pts; in diabetic, 150 is normal
Difference in believes
Not up on literature
Standards have changed
In standards
Fear
MD puts off ordering
Lowers priority for nurses
Frustrates nurses
Not all nurses value TGC
Don't understand
Don't understand
Don't think protocols work
Not enough pumps for drips
Nurse avoids drips
More frequent accuchecks
Not enough techs to do accuchecks
More work
Wasting too much blood
Too many sticks
Sympathy for the patient
Doesn't know when to switch from SS to drip
Lack of protocol
Lack of standardization
Delays start of protocol
Other priorities
Too busy
Goes off protocol
Fear of hypoglycemia
Too busy
Personal belief
Fearful
Hypoglycemia
If on protocol, MD takes off
Personal beliefs
Puts off doing it
Lack of time
Too busy
MD doesn't order
Personal beliefs
Avoids protocols
Doesn't think protocol works for everyone
Thinks will have to increase SS
Driven by different triggers
Hold different opinions
Different protocols, TX, target ranges
Too many chiefs
Different interpretations
Faculty vs. residents vs. interns
Interruptions in treatment
Orders wrong SS or drip
Personal preference
Lack of training
Computer order entry issue
Admitted without orders
Doesn't answer page
Getting admission orders
Too busy; forgets
MD not available
Lack of insulin syringes
On back order
No standardized way of dispensing
Unit to unit
PYXIS versus 446
Lack of insulin
Unit of measure to bill versus unit to treat
Delayed deliver of drip from Pharmacy
Nurse has to do
Lack of real-time lab values
Have to call for lab values
Reactive instead of proactive
MD not aware they have to do
No comment in Sunrise
That's the standard
STAT glucose takes an hour
More expensive
Glucose not considered "super-STAT"
Develops sepsis
Started on Steroids
For procedure
Protocol not followed off floor
Leaves floor
Dialysis patient
Insulin increased
Stays elevated after dialysis
Dextrose in dialysate
Level may be considered abnormal
Patient preference
Level may be considered normal
Started on TPN
Patient started on feeds
Difficult to gauge intake
Non continuous bolus
SS from floor has different triggers
Not every unit has protocol
Different MD buy in
Different trigger floor to unit
Driven by different protocols
Handled differently on floors
MD doesn't order
Won't break chain of command
Accucheck not always ordered
Protocols only on some units
Not every patient gets it
Different depts do things differently
Parm/Units (PYXIS vs. floor stock)
Inconsistent results
Some use A line; some stick pt.
Drawn differently
Nurse doesn't make drip
Not suppose to, only in emergency
Difficult to get buy-in from MD
Differ on f/u, how often, etc.
Different believes
Personal preference
No standardized policy
Too busy to sit and discuss
No agreement from MDs

Process Management (Barriers)



Barriers :

- **Survey of 269 U.S. hospitals to determine current glucose management practices**



Poster Presentation SCCM 2009: How are U.S. hospitals addressing glycemic control in their intensive care settings? Cook C., Abad V., Kongable G., Hansen Y., McMahon D.

Process Management (Barriers)

Barrier	Strategy/Solution
Insufficient glucose meters to accommodate the increased testing needs	• Purchase additional glucose meters • Ask vendor to provide extra on-site replacement meters at no charge until they are activated
Nursing time requirements involved in monitoring and adjustments	• Get ancillary help to check glucose values (eg, nurse assistants) • Make extra efforts to make protocols clear with few required calculations • Avoid duplicate recording • Consider meters requiring shorter time and a smaller sample (to avoid need for re-sampling)
Requirements for uncomfortable frequent sticks	• Utilize central lines or arterial lines –These tend to vary by <10% from POC readings –May not be available in non-critical care settings • Variable depth lancets
Staff fear of hypoglycemia	• Educate on glucose control benefit & true definition of hypoglycemia • Measure staff fasting glucose levels to demonstrate normal range • Establish metrics and publicly report hypoglycemia event rates • Pilot IIP on small scale • Protocol and education for prevention of hypoglycemia

Ahmann AJ, Maynard G. *J Hosp Med.* 2008;5(Suppl 5):42-54.

Process Management (Barriers)

Barrier	Strategy/Solution
Difficulty gaining consensus on glycemic target	• Compromise if needed on glucose target –Start with higher goal such as (90-140 mg/dL) –Others may be willing to ↓ goal when feasibility is seen • Allow for different targets in different units if indicated –Maintain consistency in other respects
Focal points of resistance	• Identify local nurse or physician champion within resistant site • Pilot protocol in an area with least resistance –Will gain momentum with initial success and adjustments
Lack of integrated information and reporting systems	• Incorporate information systems personnel onto team • Advocate for ↑ reporting capability with administrative leaders • Use sampling methods to collect data until automated systems are available
Multiple providers, hand offs, and opportunities for error and communication breakdown, diffusion of responsibility for glycemic control	• Involvement of varied front line providers • Check lists for important items to communicate on transfer/transport • Common protocols/education for similar units

Ahmann AJ, Maynard G. *J Hosp Med.* 2008;5(Suppl 5):42-54.

Process Management (Barriers)

Iatrogenic Hypoglycemia

- **Critical Thinking**
  - NPO/Feeds held/Regular Diet
  - Dialysis
  - IVF changed
- **Medication Errors**
  - Wrong dose
  - Failure to change insulin dosing
- **Missed Care**
  - Infrequent glucose monitoring

Medication Management

- Yale
- Leuven
- Portland
- Digami
- University of Washington
- Rush University
- Northwestern University

Protocols

Medication Management

- Develop protocol
  - Prompt users to initiates drip
  - Permits titration by ICU nurses
  - Ensure continuous administration of glucose
  - Specifies frequency glucose monitoring
  - Specify treatment plan for hypoglycemia.
  - Ensure nurses can handle increased burden of frequent glucose checks
  - Transition to subcutaneous insulin

Medication Management: Insulin Preparations

- **Human**
  - Rapid Acting
    - Lispro
    - Aspart
    - Glulisine
  - Short Acting
    - Regular
  - Intermediate Acting
    - Lente
    - NPH
  - Long Acting
    - Insulin glargine analog Detemir
    - Ultralente

- **Human**
  - Pre-mixed
    - Humalog™ 75/25 Novolog Mix™ 70/30
    - Humulin™ 70/30 Novolin™ 70/30

- Animal Source
  - Regular
  - NPH
  - Lente

National Diabetes Education Program. Http://www.ndep.nih.gov/diabetes/wtmd/diabets_suppl_2.htm

Medication Management

- Continuous variable rate IV drip
  - Regular Insulin
  - Continue IV Insulin until patient tolerating food/feeds
  - Continue IV Insulin at least 2 hrs after 1st SC Insulin dose given (longer if basal Insulin)
- Options to consider for transition:
  - Regular insulin sliding scale – not effective
  - Premixed Insulin (Basal only)
  - Basal-bolus
    - Long acting Insulin and rapid acting Insulin
- Oral hypoglycemic agents
  - Stable patients eating (stability in nutrition & condition)
  - Not appropriate

ACE/ADA Consensus Statement, Endocrine Practice.2006:12(4)459-468

Medication Management

- Education
  - Physicians
  - Nurses
  - Techs
- Cook (2008)
  - S/S vs IV
  - Options/works?
  - Policies/protocols?
  - Target ranges?

Cook C et al. Beliefs About Hospital Diabetes and Perceived Barriers to Glucose Management Among Inpatient Midlevel Providers. The Diabetes Educator. 2008;34(1):75-83

Data Management (Metrics)

- Identify Program Goal
  - 80-110, 80-140
  - What are you comfortable with?
- Identify how to measure metrics/compliance
  - Who: QA department, nurse, director, lab, POC office
  - How: Chart, crystal or lab report, data mining software
  - When: Shift, daily, weekly, monthly, or quarterly
- Identify what to measure
  - Mean value (basic) good for trending
  - % values in range (basic) good for trending
  - % time in range/ range by patient

Data Management

How well are we doing?

Decrease in Mean Blood Glucose

Mean based on values 80-600

- 2003 156.1
- 2004 139.5
- 2005 130.8

We thought we were doing a great job!!

- **Survey on Glycemic Control in Hospitals: 30% of ICU patients mean BG > 180 mg/dL**

Nursing Survey before TGCM

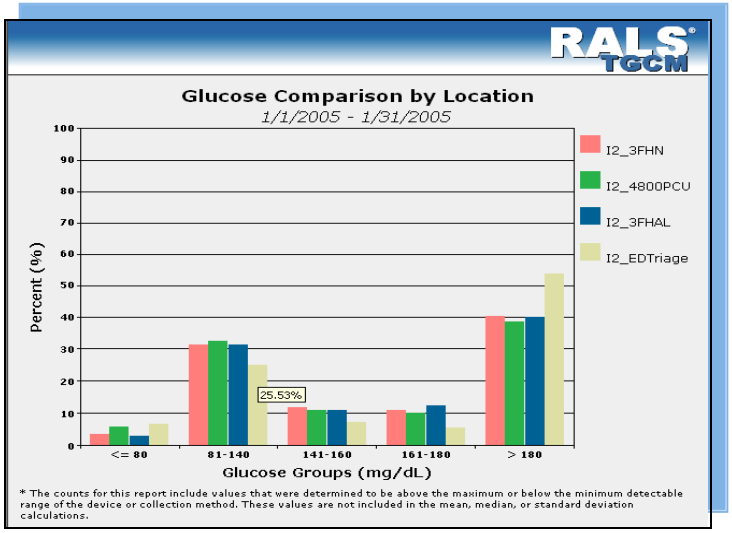
- A TGC survey was developed to evaluate the nursing staff's:
  - Knowledge of existing protocol.
  - **Perceived percentage of effectiveness in achieving target range.**
  - Perceived barriers to TGC.
  - Knowledge of available research literature on TGC.
  - Knowledge of benefits related to TGC.

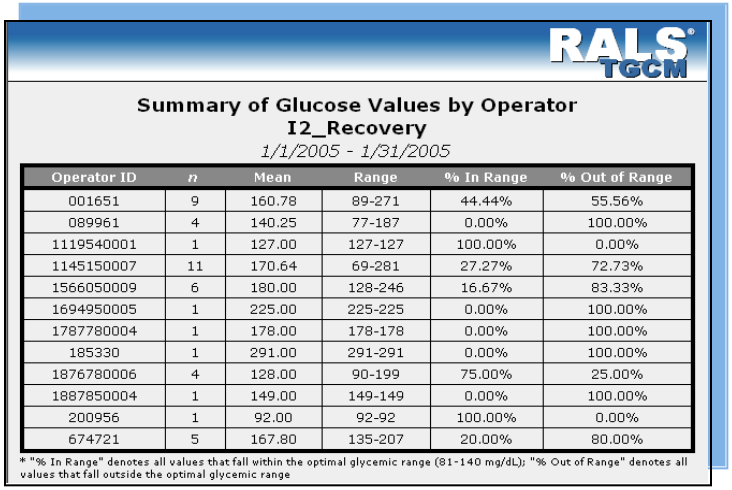
- 57 nurses, 92.3% participated in the survey.
  - 100% knew of the protocol and target range.
  - **86% believed they kept patients in target range 50% to 90% of the time**
  - **59% believed they achieved target range 70-90% of the time**

- **Our Survey Results:**
  - **STICU patients achieved target range 38% of the time**

Implementation Data Management RALS-TGCM

- Monitor, assess, and reassess
  - Daily, Weekly, Monthly
- Share the results
  - E-mail
  - Bulletin board
  - Staff meeting

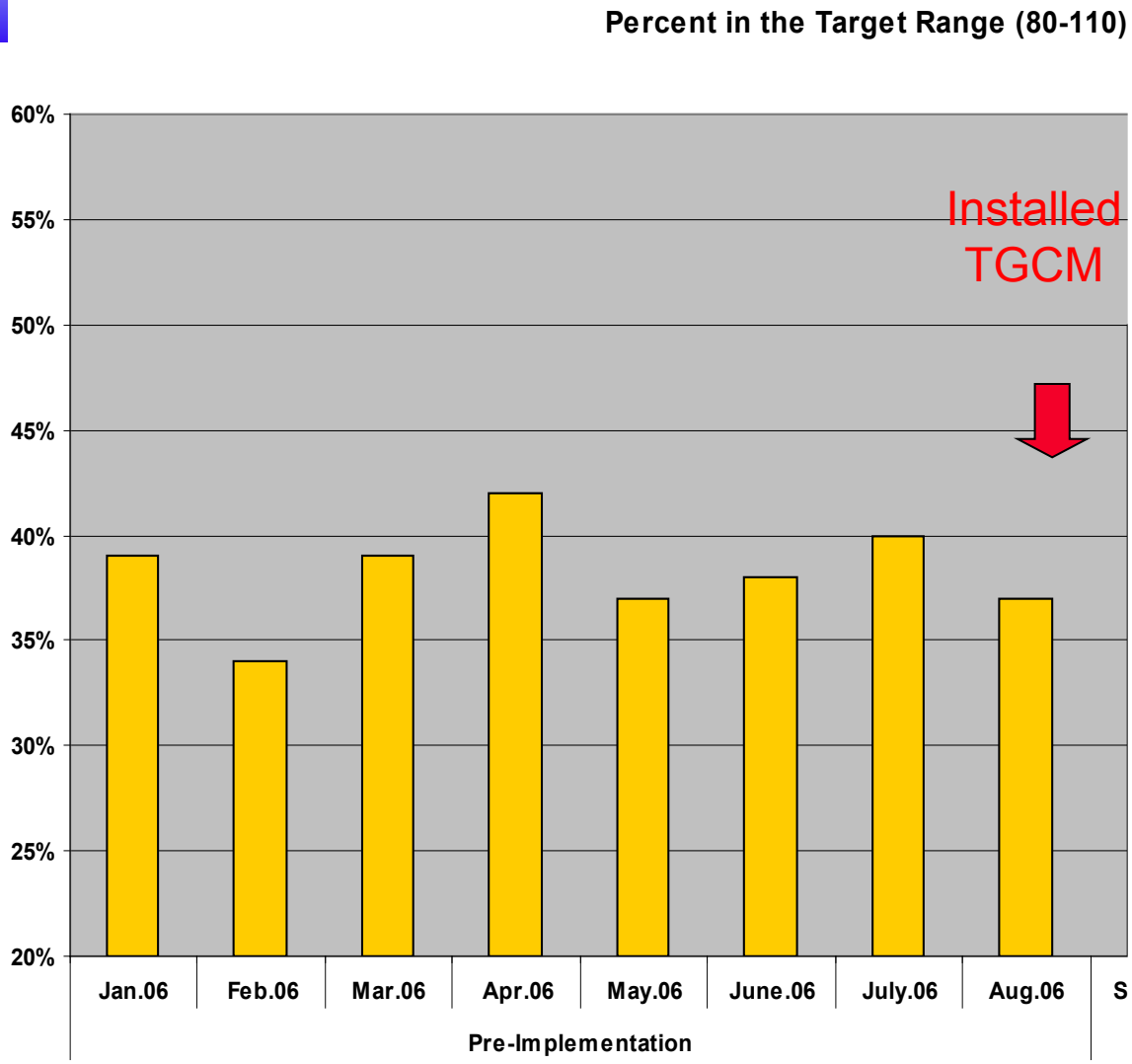




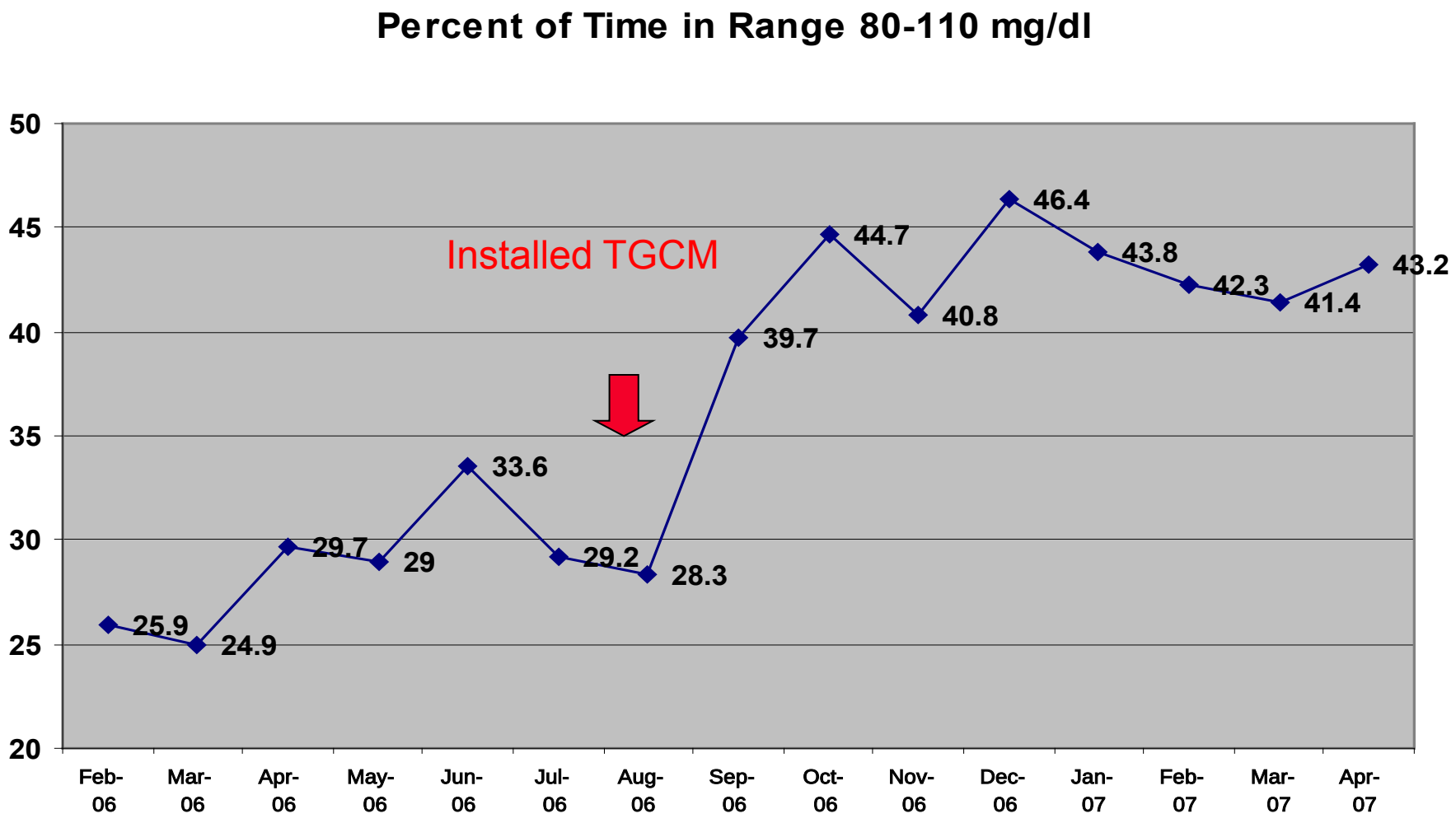
Operator ID	n	Mean	Range	% In Range	% Out of Range
001651	9	160.78	89-271	44.44%	55.56%
089961	4	140.25	77-187	0.00%	100.00%
1119540001	1	127.00	127-127	100.00%	0.00%
1145150007	11	170.64	69-281	27.27%	72.73%
1566050009	6	180.00	128-246	16.67%	83.33%
1694950005	1	225.00	225-225	0.00%	100.00%
1787780004	1	178.00	178-178	0.00%	100.00%
185330	1	291.00	291-291	0.00%	100.00%
1876780006	4	128.00	90-199	75.00%	25.00%
1887850004	1	149.00	149-149	0.00%	100.00%
200956	1	92.00	92-92	100.00%	0.00%
674721	5	167.80	135-207	20.00%	80.00%

* "% In Range" denotes all values that fall within the optimal glycemic range (81-140 mg/dL); "% Out of Range" denotes all values that fall outside the optimal glycemic range

Percent of Values in Target Range (80-110)

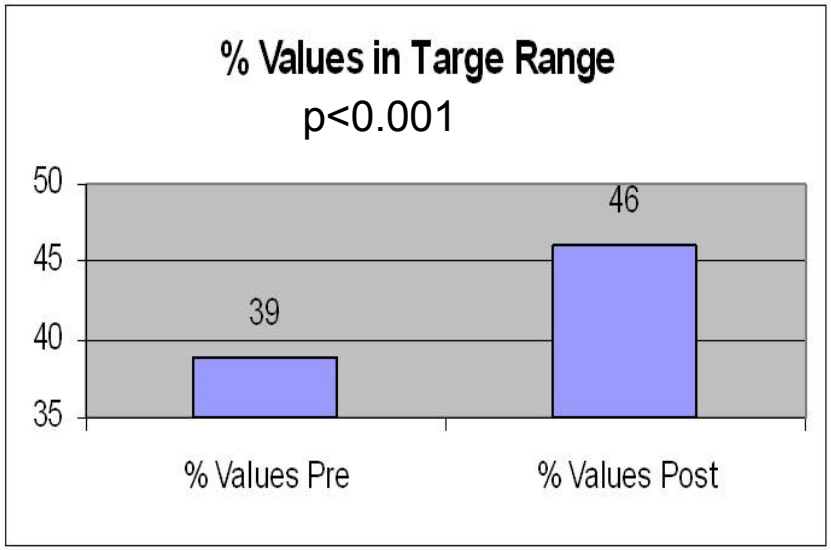


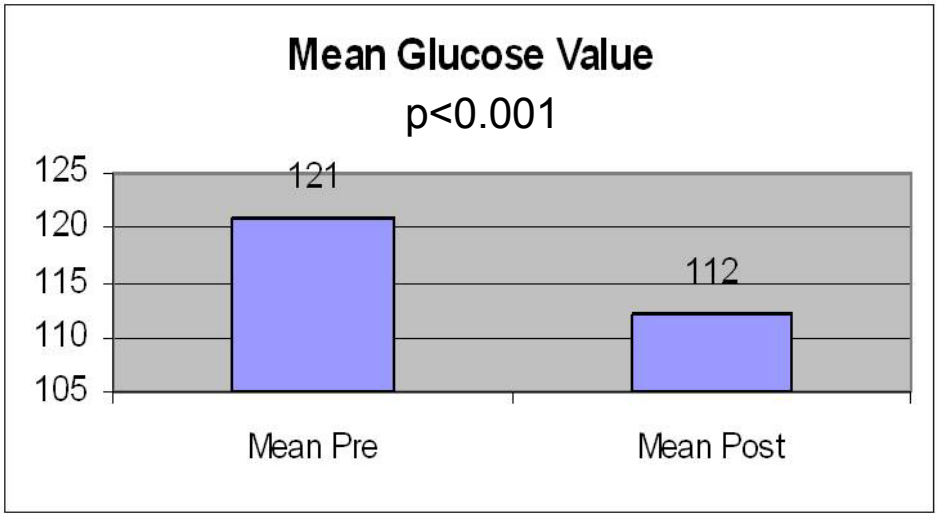
Patient in Target Range of (80-110 mg/dL)

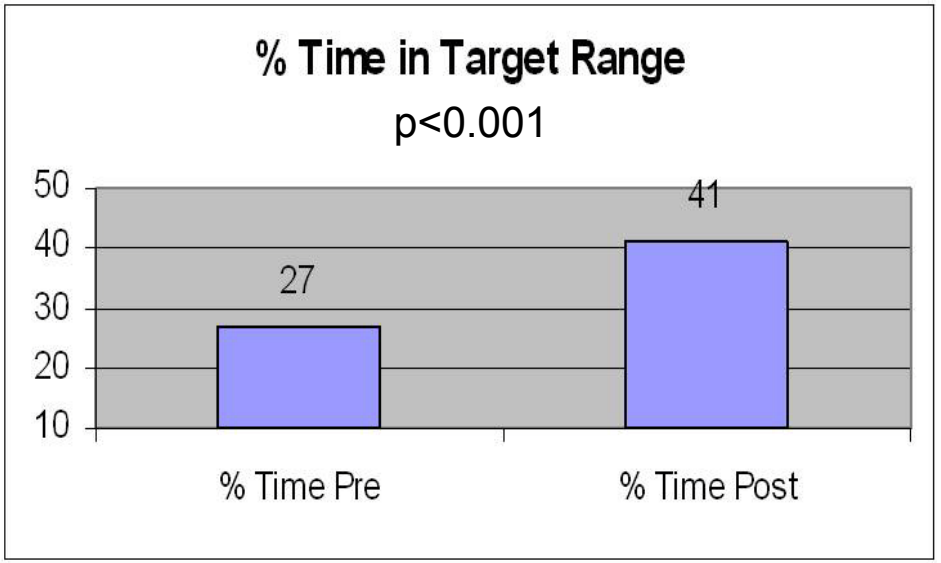


Study Results

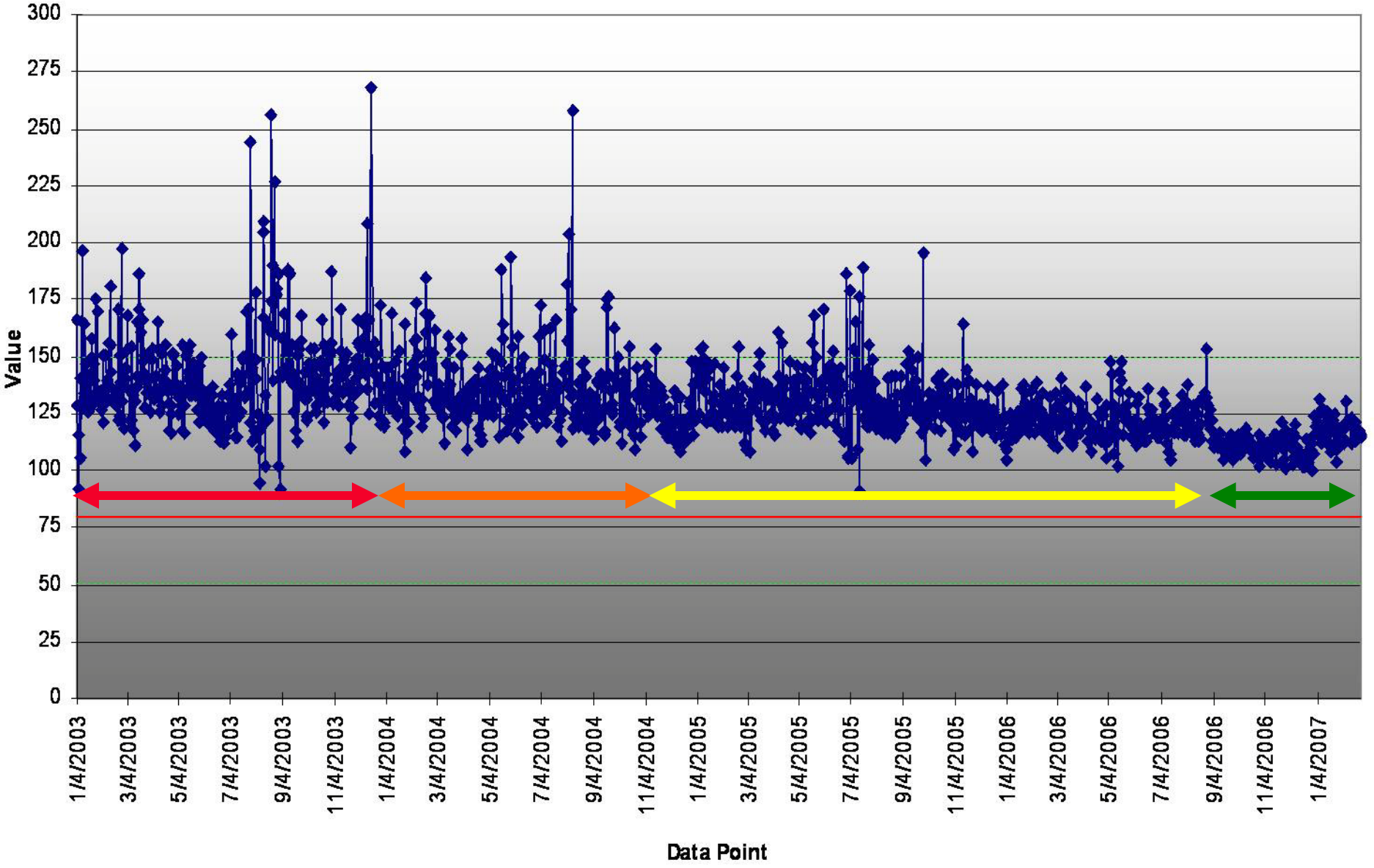
91,536 glucose results collected







Presented at SCCM 2008


Average Daily Glucose Levels
January 2003- February 2007
300
275
250
225
200
175
150
125
100
75
50
25
0
Value
1/4/2003
3/4/2003
5/4/2003
7/4/2003
9/4/2003
11/4/2003
1/4/2004
3/4/2004
5/4/2004
7/4/2004
9/4/2004
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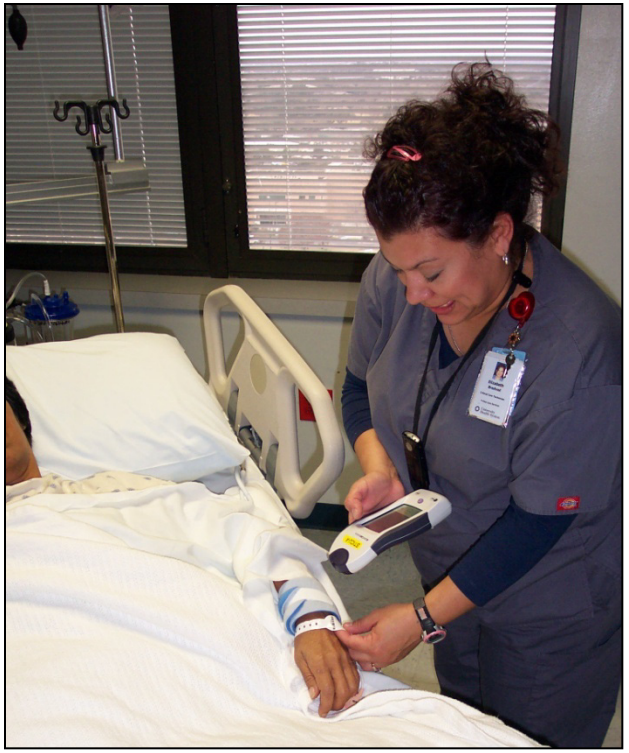
9/4/2005
11/4/2005
1/4/2006
3/4/2006
5/4/2006
7/4/2006
9/4/2006
11/4/2006
1/4/2007
Data Point

Benefits of a Data Mining Software Program: RALS-TGCM

- Overcomes the barrier of limited visibility to data
- Real-time display of glucose control data
- Glucose trends to those caring for patients
- Access to prospective blood glucose data
- Potential protocol improvement & adherence

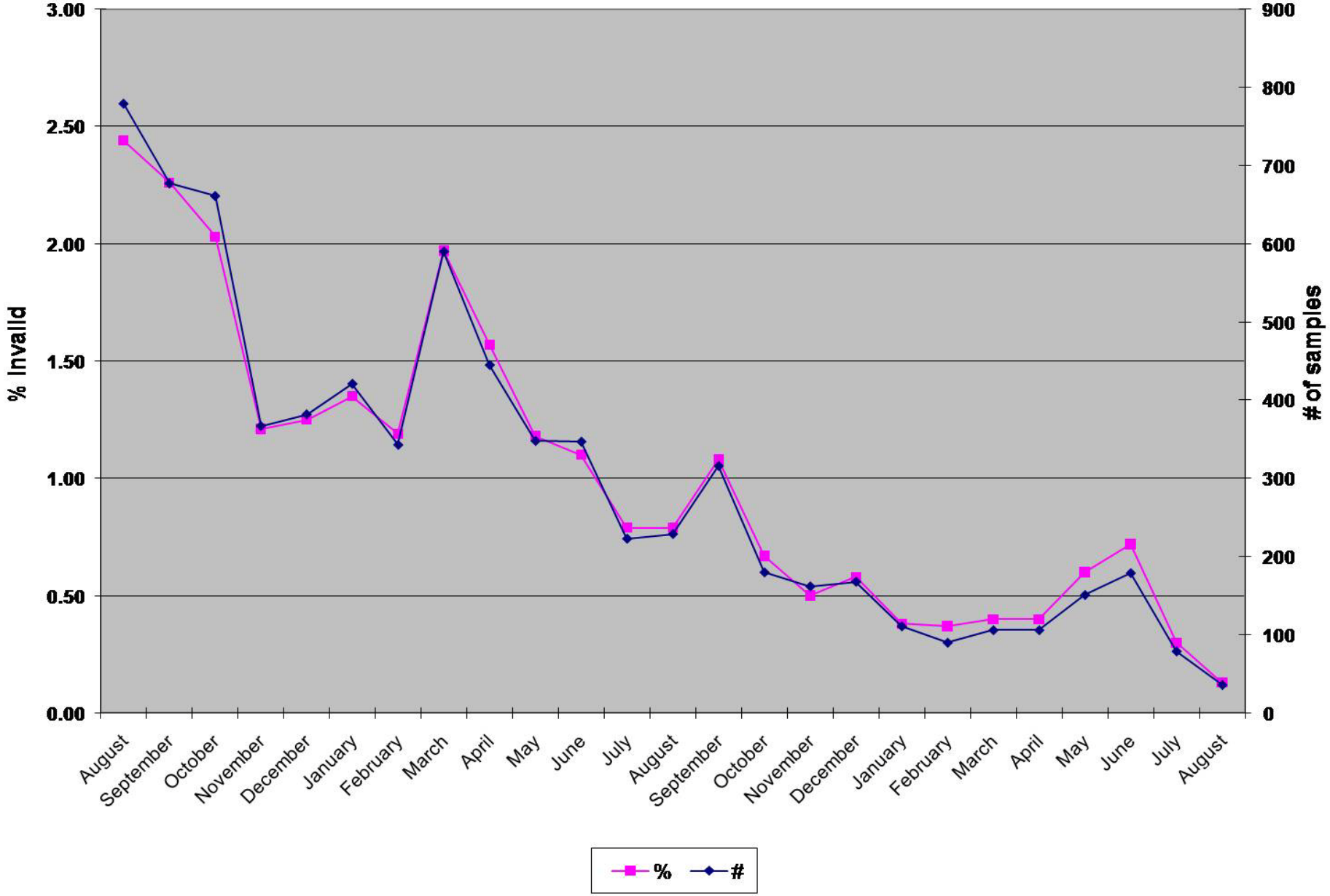
Reducing Invalid Results

- Matheny (2007)
  - 3616 diabetic patients
    - 613 Lacking POC BG two days
- Colard 2004
  - St. Lukes Hospital Kansas City MO
  - 12,000 POC BG tests month
    - 400-500 (up to 12.4%)
    - 274 4.9%
    - 102 1.7%
    - 6 .18%



Matheny M et al. Treatment Intensification and Blood Glucose Control Among Hospitalized Patients. J Gen Intern Med. 2007;23(2):184-189 Colard D. Reduction in Patient Identification Errors Using Technology. 2004 Clinical Lab Expo AACC

Invalid POC Blood Glucose



AACE & ADA Summary of Recommendations 2009

- Glycemic Control Critically ill
  - Start treating hyperglycemia 180
  - Target range 140-180mg/dL
  - IV insulin
  - Validated protocols
  - Frequent glucose monitoring
- Glycemic Control Noncritically ill
  - Target: Premeal <140, random <180mg/dL

Diabetes Care. 2009; 32(6):1119-1131

AACE & ADA Summary of Recommendations 2009

- Safety issues
  - Over and under treatment of hyperglycemia major safety concern
  - Education
  - Caution interpreting in select populations
  - Buy-in and financial support
- Cost
  - Cost-effective

Diabetes Care. 2009; 32(6):1119-1131

AACE & ADA Summary of Recommendations 2009

- Discharge planning
  - Transitioning begins at admission
  - Discharge planning, education, communication

Diabetes Care. 2009; 32(6):1119-1131

AACE & ADA Summary of Recommendations 2009

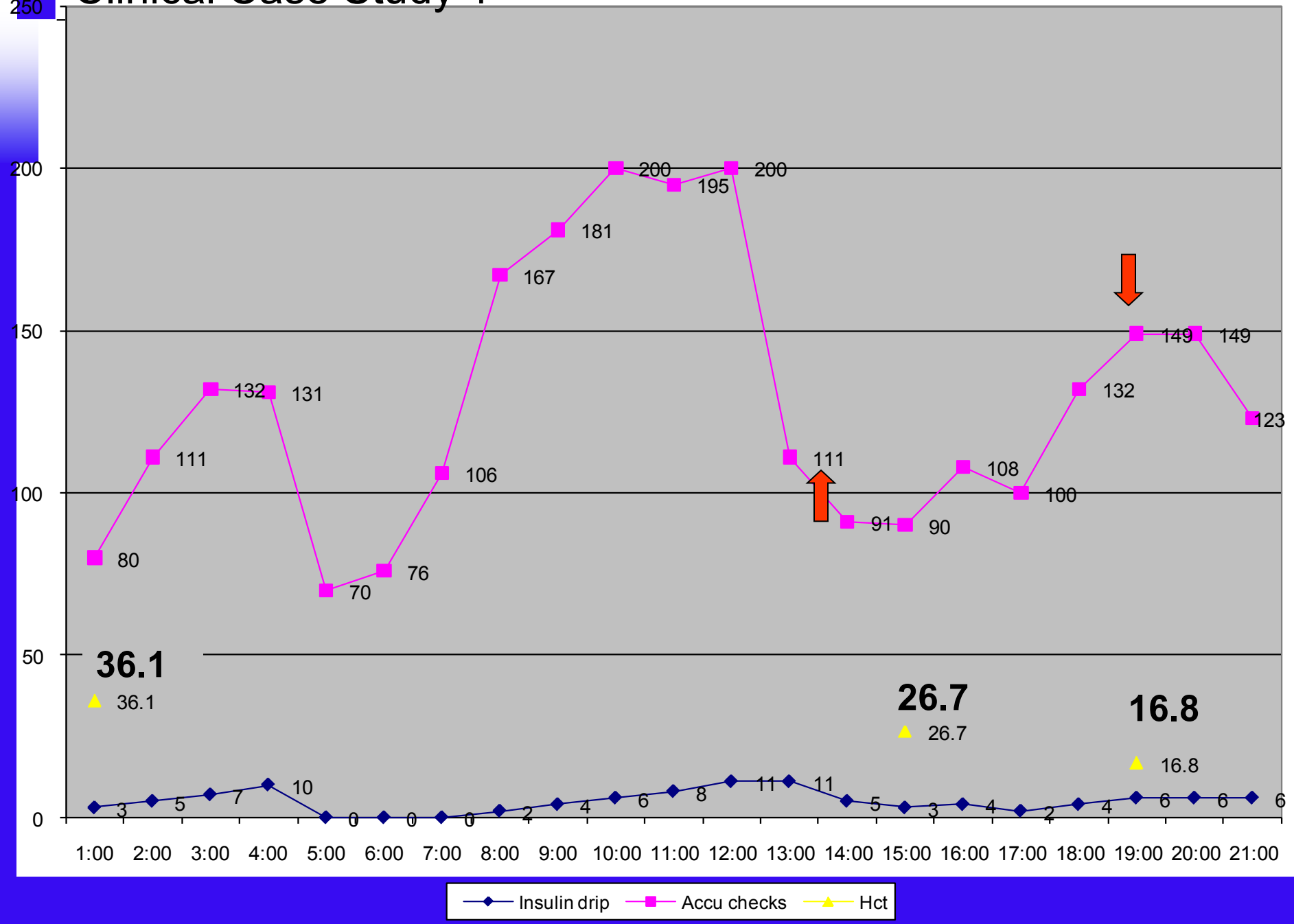
- Areas of future research
  - **Stress hyperglycemia**
  - Severe hypoglycemia
  - Glycemic targets on general wards
  - **Glycemic variability**
  - Hospital systems and safety
  - Insulin treatment and monitoring
  - Pediatric inpatient populations

Diabetes Care. 2009; 32(6):1119-1131

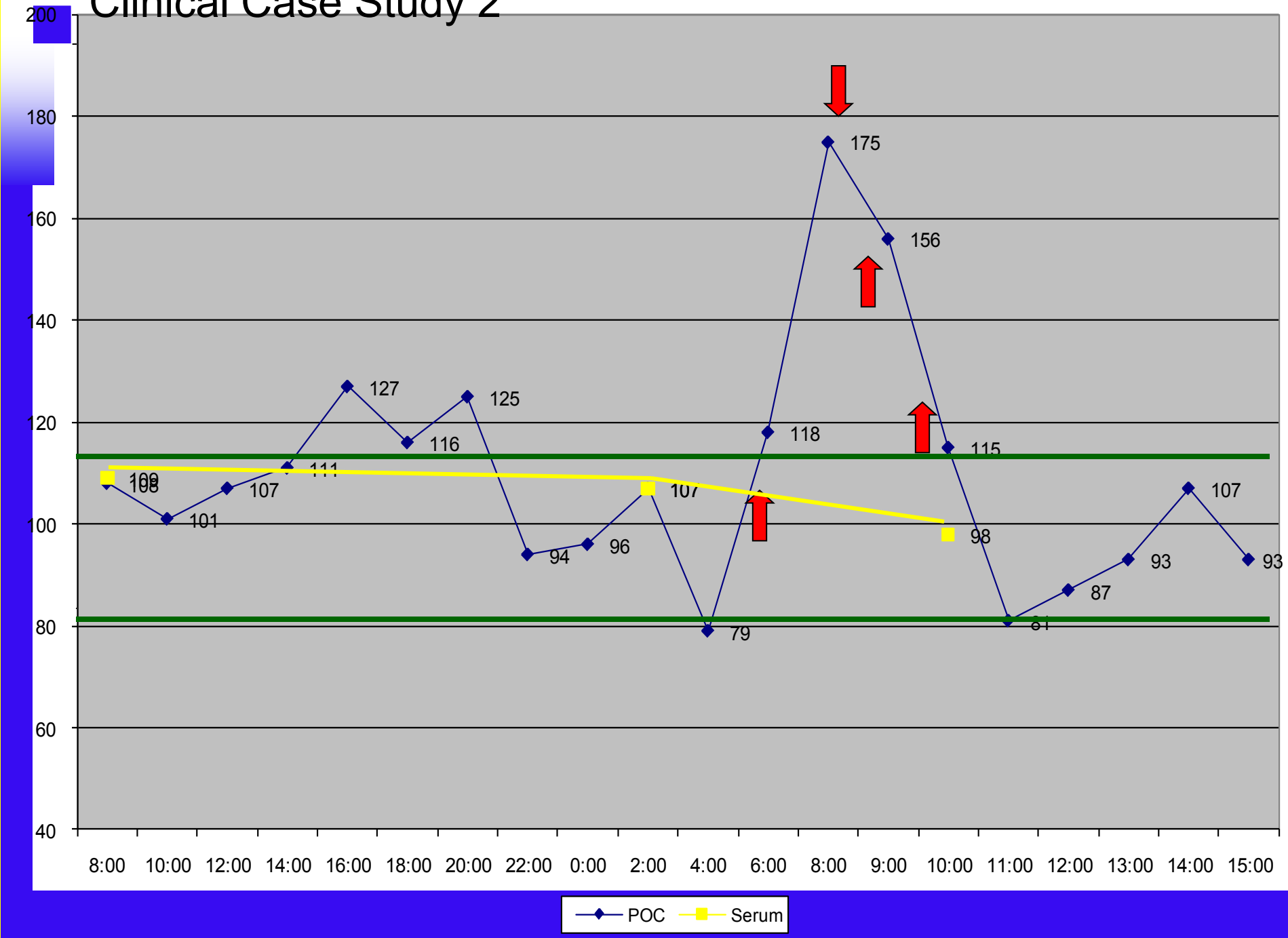
Case Studies: Glucose more than just a value

- Glucose Variability
- Utilizing hyperglycemic episodes as a patient indicator for a worsening condition:
  - Bleeding
  - Sepsis
- Failure to Rescue
  - Careful surveillance and timely identification of complication
  - Initiating appropriate intervention and notifying the team

Clinical Case Study 1



Clinical Case Study 2



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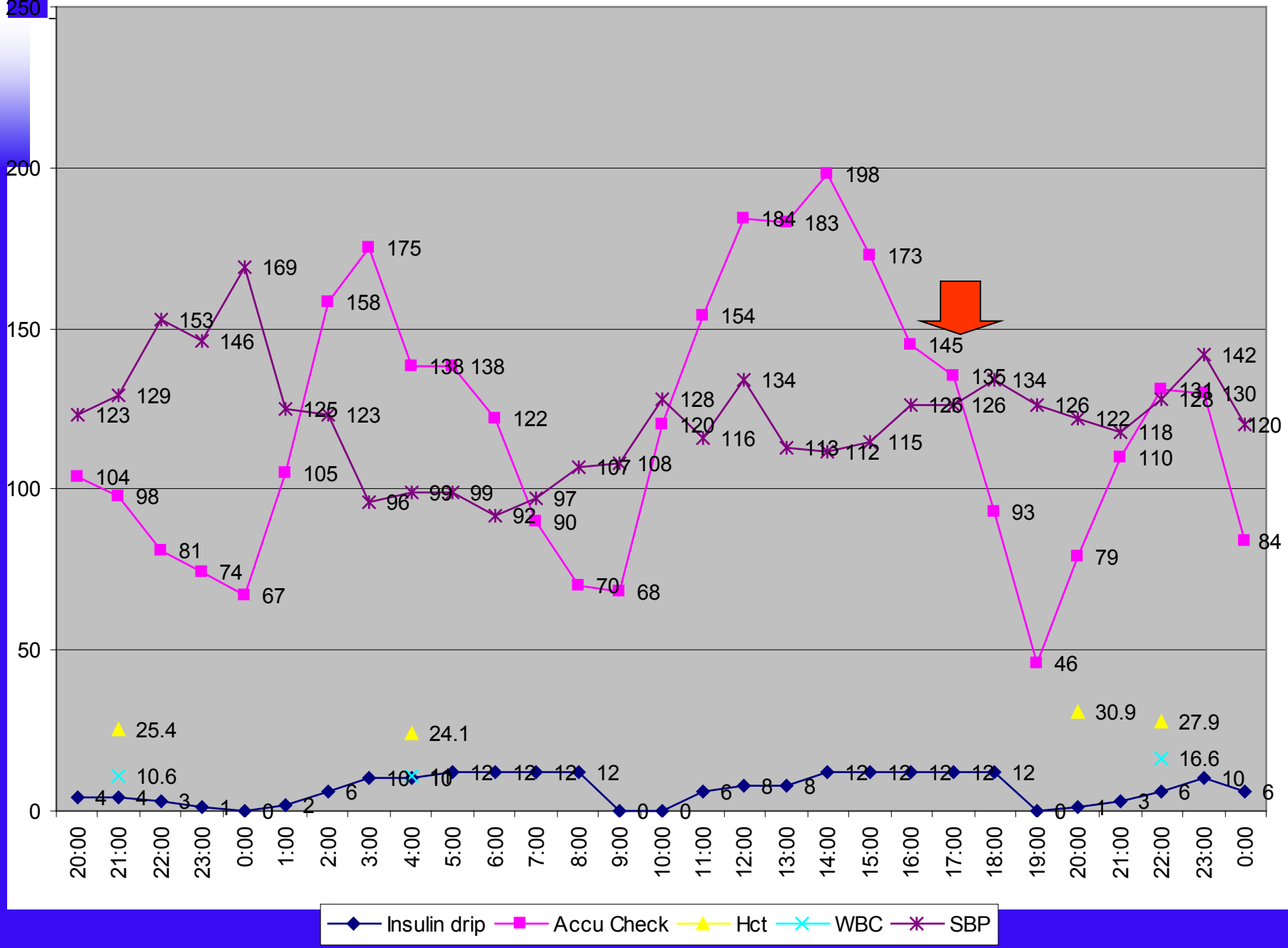

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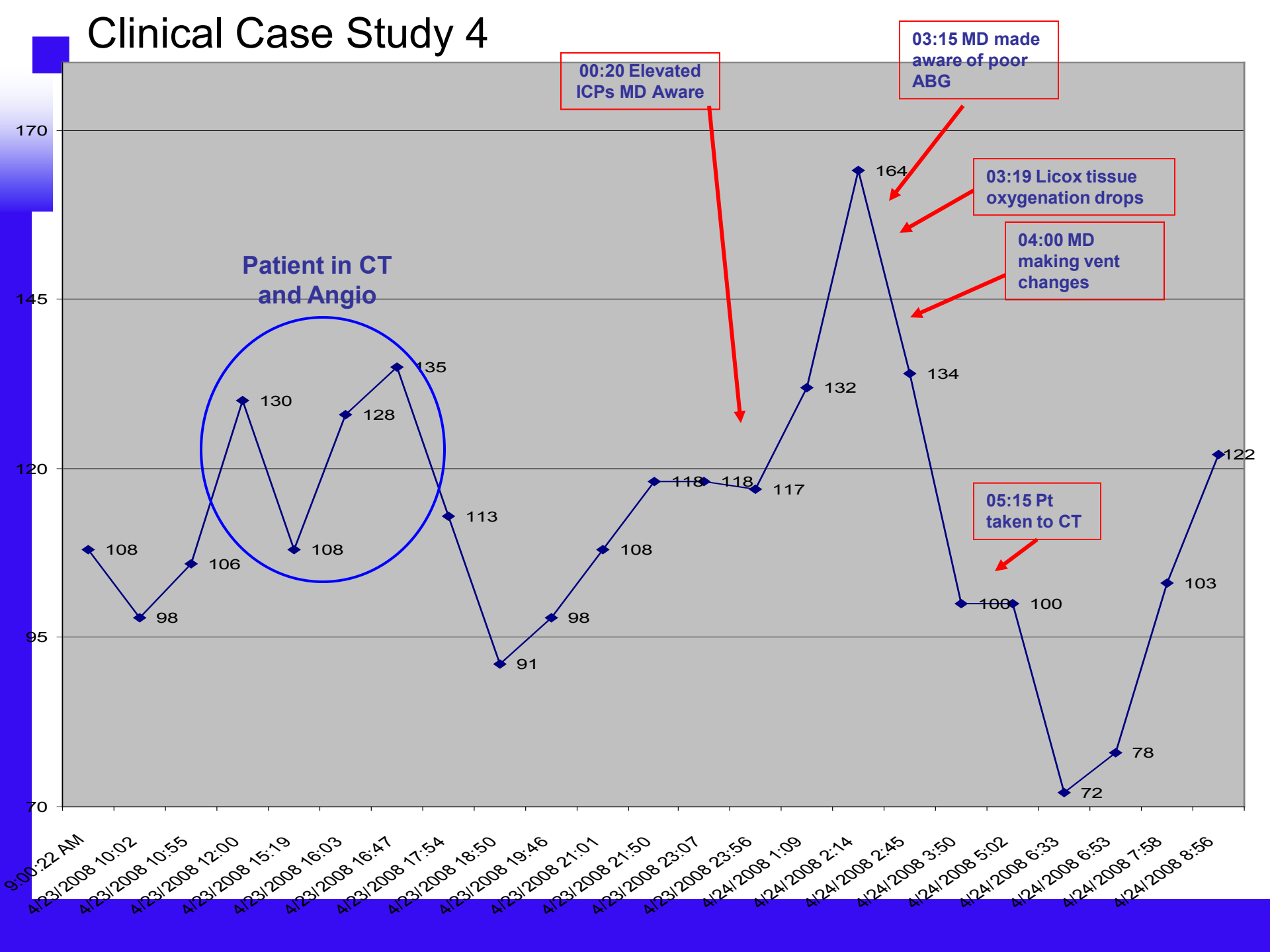

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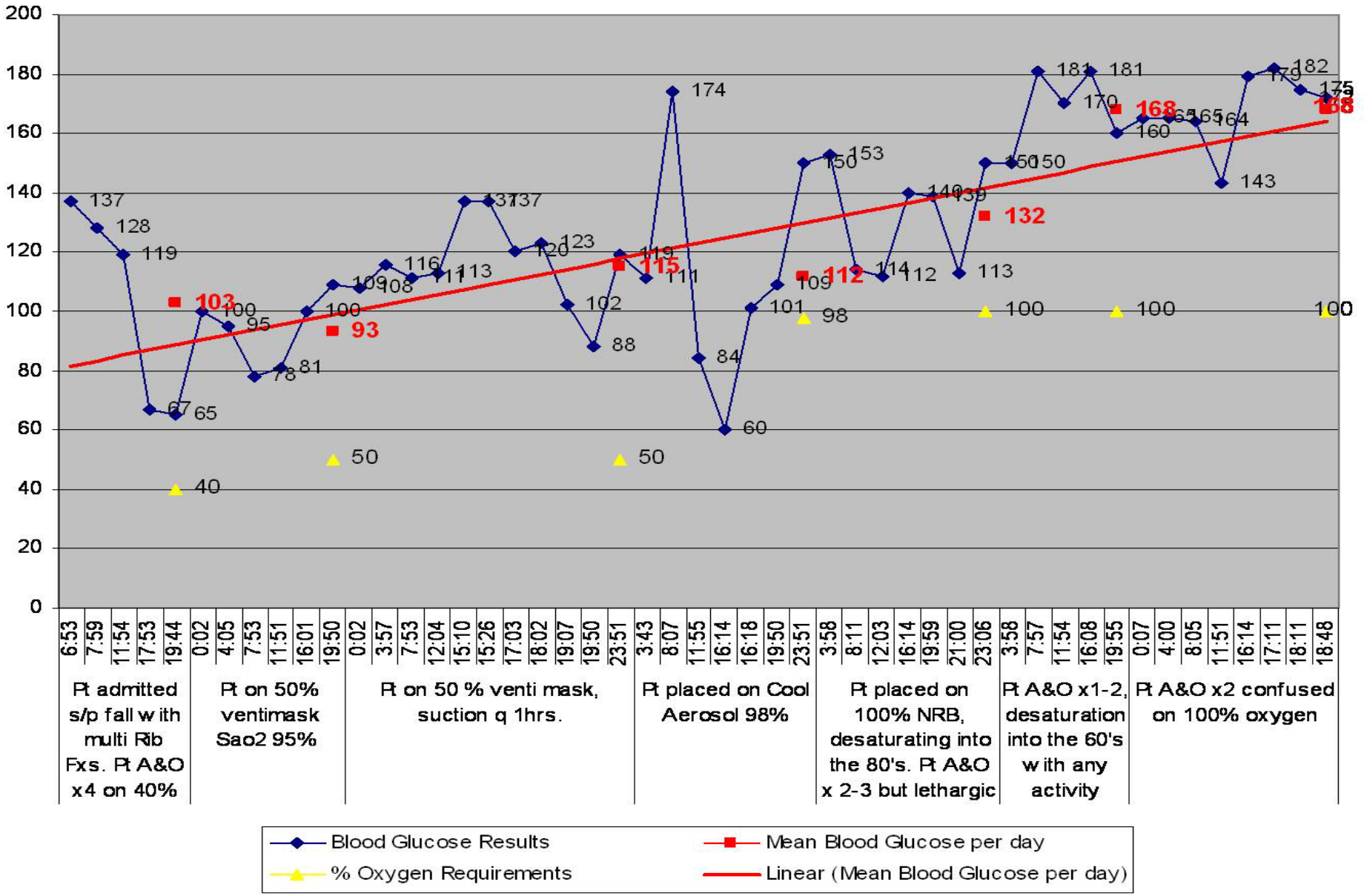
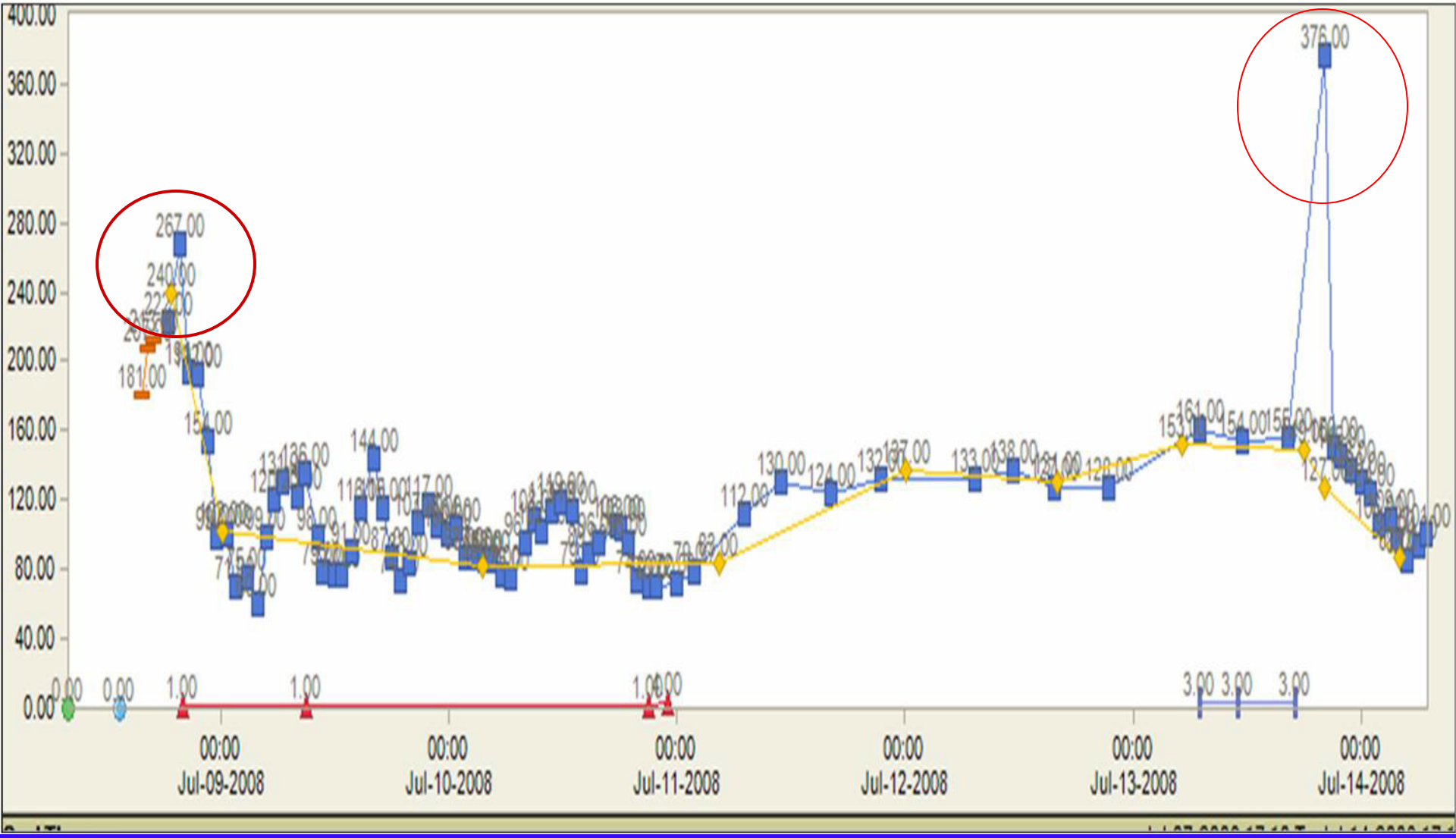


Clinical Case Study 6



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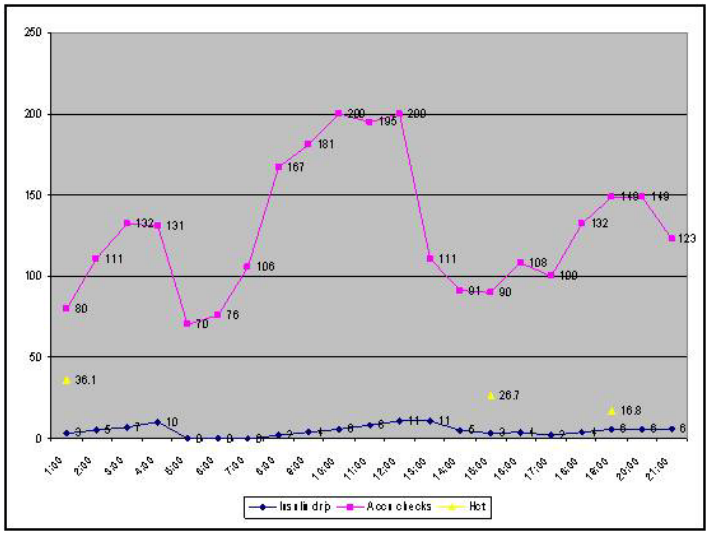

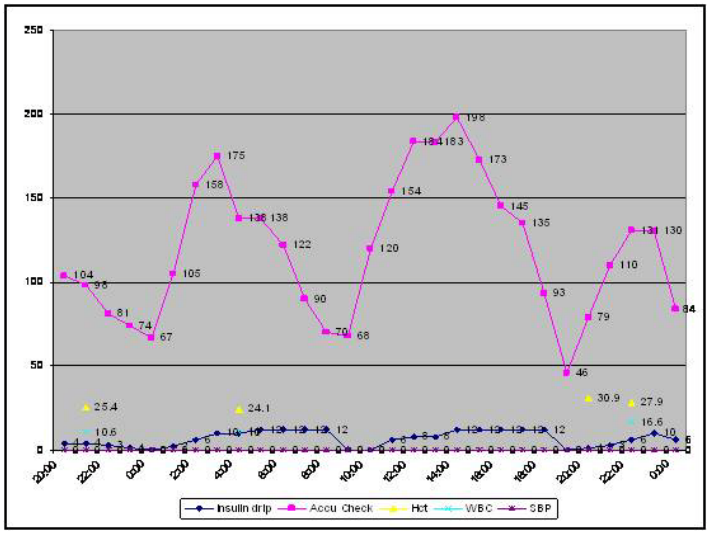

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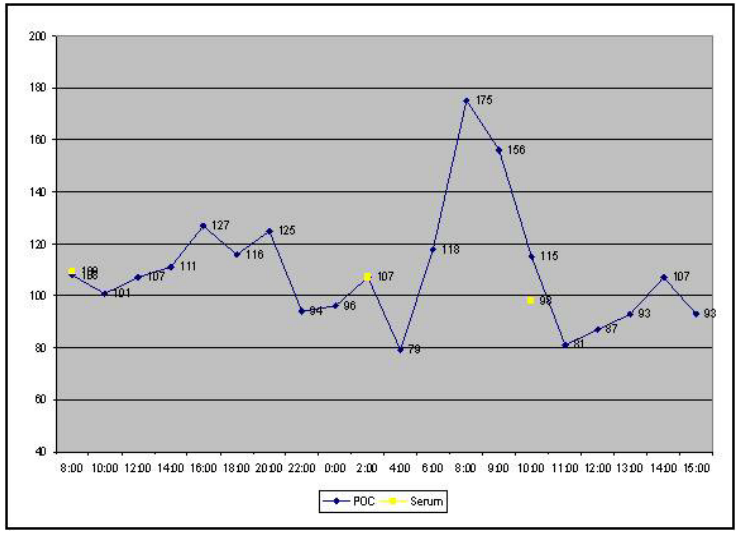

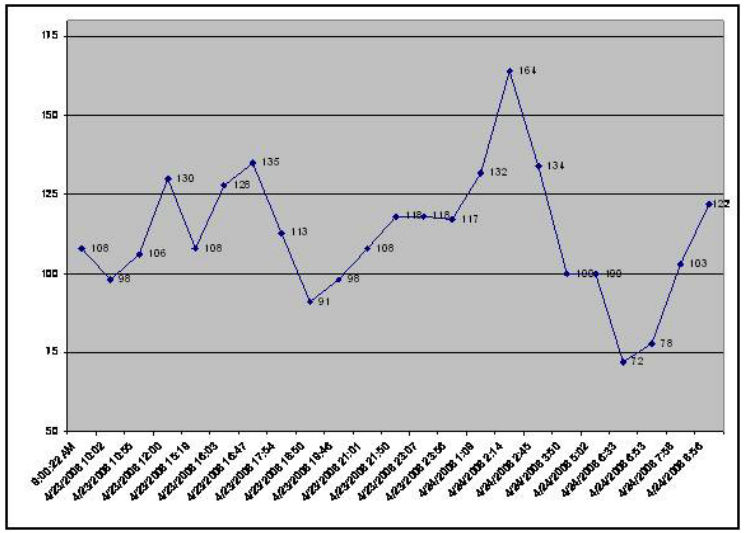

Journal of American College of Surgeons

Intensive Insulin Protocol Improves Glucose Control and Is Associated with a Reduction in Intensive Care Unit Mortality

Charles C Reed, BSN, Ronald M Stewart, MD, FACS, Michele Sherman, BSN, John G Myers, MD, FACS, Michael G Corneille, MD, FACS, Nanette Larson, BSN, Susan Gerhardt, MSN, Randall Beadle, BSN, Conrado Gamboa, MS, RPh, Daniel Dent, MD, FACS, Stephen M Cohn, MD, FACS, Basil A Pruitt Jr, MD, FACS

BACKGROUND: Intensive insulin therapy to maintain serum glucose levels between 80 and 110 mg/dL has previously been shown to reduce mortality in the critically ill; recent data, however, have called this benefit into question. In addition, maintaining uniform, tight glucose control is challenging and resource demanding. We hypothesized that, by use of a protocol, tight glucose control could be achieved in the surgical trauma intensive care unit (STICU), and that improved glucose control would be beneficial.

STUDY DESIGN: During the study period, a progressively more rigorous approach to glucose control was used, culminating in an implemented protocol in 2005. We reviewed STICU patients' blood glucose levels, measured by point-of-care testing, from 2003 to 2006. Mortality was tracked over the course of the study, and patient charts were retrospectively reviewed to measure illness and injury severity.

RESULTS: Mean blood glucose levels steadily improved ($p < 0.01$). In addition to absolute improvements in glucose control, total variability of glucose ranges in the STICU steadily diminished. A reduction in STICU mortality was temporally associated with implementation of the protocol ($p < 0.01$). There were fewer intraabdominal abscesses and fewer postinjury ventilator days after implementation of the protocol. There was a small increase in the incidence of clinically relevant hypoglycemia.

CONCLUSIONS: Improvements in glucose control in the ICU can be achieved by using a protocol for intensive insulin therapy. In our ICU, this was temporally associated with a significant reduction in mortality. (J Am Coll Surg 2007;204:1048–1055. © 2007 by the American College of Surgeons)

Insulin resistance and hyperglycemia are extremely com-

Texas Medical Branch at Galveston (UTMB) have demon-