

The CompuRecord® System From Electric Pencil to The American Dream

-Chester A. Phillips III, M.D.

Content Outline

- Dr. Gravenstein and Dr. Phillips
- The bittersweet / high point – June 15th, 2000
- The journey – 1977 to 2000
 - Genesis: research – build a database for research
 - Morph to a business
 - FDA
 - PPG
 - In business alone
 - HP Medical (became Agilent Technologies then Philips Healthcare)
- Results from the use of our tool

Dr. J. S. “Nik” Gravenstein

- Well-known Academic Anesthesiologist
- Founder of Department, University of Florida College of Medicine
- Chairman and Professor, Case Western Reserve
- Graduate Research Professor of Anesthesia, University of Florida
- Co-Founder, Anesthesia Patient Safety Foundation
- Co-Founder, Society for Technology in Anesthesia
- Father of the Patient Simulator

Dr. Chester A. Phillips, III

- Private Practice Clinician
- Chief, Cardiac Anesthesia Section in a busy private practice
- Chairman, Anesthesia Department in a suburban hospital
- Associate Examiner, American Board of Anesthesia
- Inventor of the CompuRecord Anesthesia Information System
- Co-Founder (with wife Judy) Anesthesia Recording, Inc.
- Pioneer of Automated Record-Keeping in Anesthesia

June 15th, 2000 – a bittersweet moment

- PBS Nightly Business Report – Paul Kangas



Genesis – In the beginning ...

- The Challenge
 - Publish research articles in Anesthesiology about humans, not about goldfish
 - Collect Data and build a database
 - Manually
 - Hand-kept anesthesia record
 - Computer - 1977
 - Whoops – data needs a context: events and drugs
 - Harness the users: Use the computer and it will print your record
 - January, 1979 – Recordkeeper installed, Mercy Hospital of Pittsburgh
 - (Context – the IBM PC was introduced in August, 1981)

Morph research project to a Business

- Trying to get others to use it
- To the shows (Heathkit, ...when finished, electric pencil)
- Incorporation – Anesthesia Recording, Inc.
- FDA
 - Medical Device regulation
 - 510K Premarket Notification
 - Medical Device Manufacturer
- Our First FDA Inspection
- First Sale
- First Sale out of town

PPG Biomedical Systems Partnership

- PPG Biomedical Systems (1990 - 1993)
 - The SARAcap System
 - Partnership
 - Used their Salesforce to sell CompuRecord
 - Monthly retainer – a draw against future commissions
 - A few systems (Mt. Sinai in New York, Children's Hospital of Philadelphia)
 - Leadership change at PPG – Partnership ends
 - The Good
 - Income allowed us to hire engineers
 - further system development
 - National Exposure
 - The Bad
 - We were alone

The Business Years (1994 – 1999)

- Crunch Time – a tiger by the tail
 - ARI had a payroll to meet – responsibilities
 - Customers – doing research – who needed support & further development
 - Sales channel had to be developed
 - Backup capital source: Judy and Chester's family checking account
 - Creative Finance - Liberace to the rescue

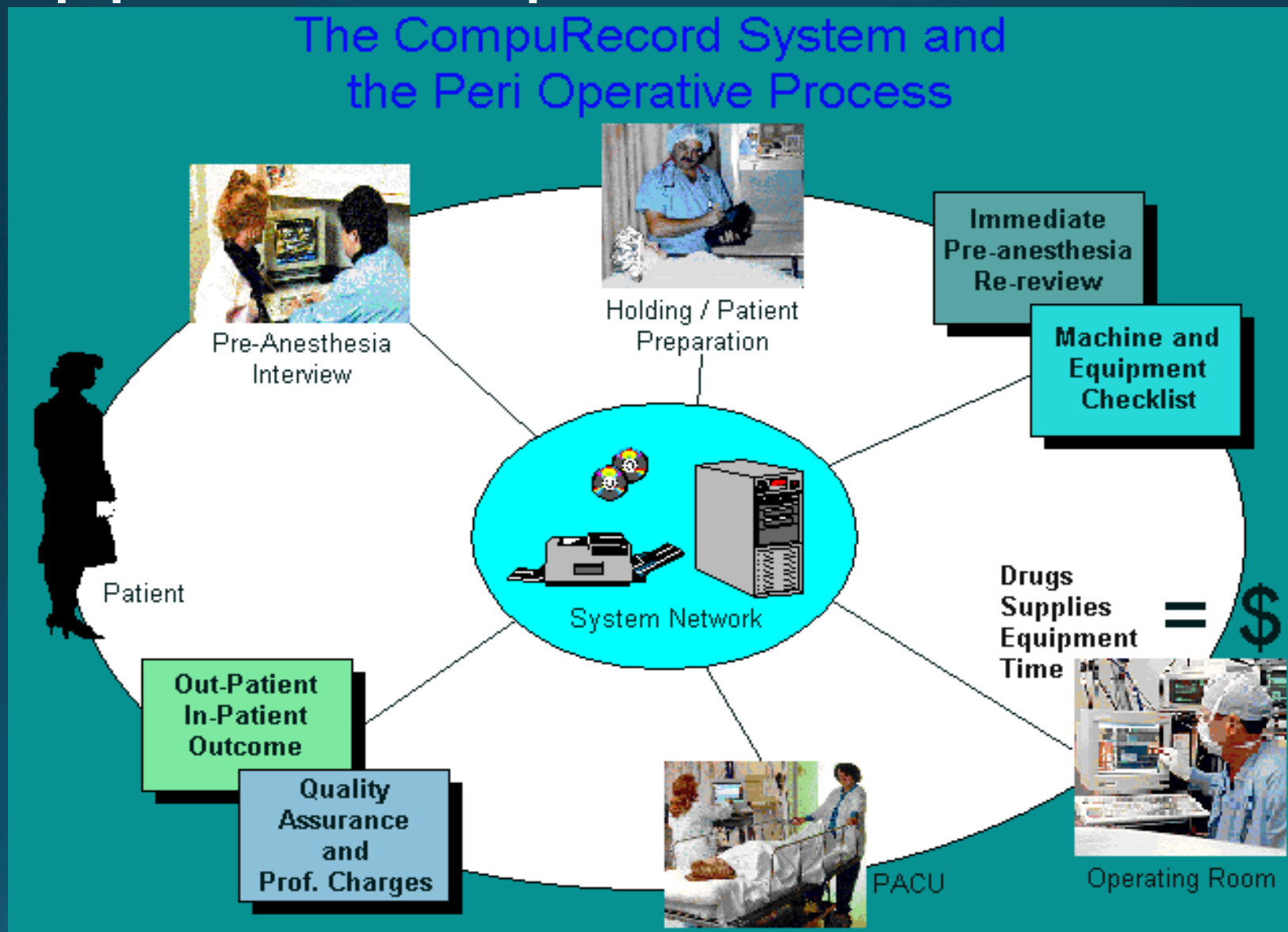
Liberace and St. Francis



Work to make it take off

- Work to make it take off
 - Customers published research – surely this will spur interest
 - Successful port to Windows and C++
 - ASA Meeting trade shows
 - Venture Capital Investors ...

Add "Apps" – complete the circle



Enter HP Medical

- HP Medical Division
 - Medical Monitors
 - ECG Machines
 - Echo machines (we used for TEE)
 - CareVue computerized record for ICU care
- Their interest in CompuRecord
 - Utilize existing sales channel
 - Strengthen their CareVue offering
 - Help their monitor sales
- Acquisition – July 1st, 2000
 - Judy and Chester don't own it any more

t's About the Database

What Data to Collect?

- “More is never enough, too much is usually just right.”
- Include the WHOLE perioperative process, not just the intra-operative portion.
- Must encompass ALL cases, not just some of them
 - You never know which case will be important
- Need an open database that supports research

Investigate an Incident

- Department of Surgery, March 14
- "...That afternoon he was brought back to the operating room for surgery and again put to sleep, however he experienced hypoxia and expired in the operating room. Mechanisms as to the cause of his death were discussed. These mechanisms included ... endotracheal tube dislodgement..."

Time	Heart Rate	Sys AP	Dias AP	EtCO2	SpO2
13:34:30	60.0	96.0	54.0	33.2	98.0
13:34:45	61.0			33.1	98.0
13:35:00	61.0			32.7	98.0
13:35:15	60.0			32.9	97.0
13:35:30	60.0	95.0	57.0	33.1	98.0
13:35:45	60.0			32.5	97.0
13:36:00	61.0			32.7	97.0
13:36:15	61.0			31.1	98.0
13:36:30	61.0	83.0	47.0	33.0	98.0
13:36:45	61.0				98.0
13:37:00	58.0			29.9	98.0
13:37:15				30.4	
13:37:30				30.1	
13:37:45	45.0			28.8	97.0
13:38:00	44.0			29.1	96.0
13:38:15	42.0			28.7	96.0

Time	Heart Rate	Sys AP	Dias AP	EtCO2	SpO2
13:38:30	41.0	67.0	54.0	28.1	95.0
13:38:45	41.0			23.4	94.0
13:39:00	41.0				92.0
13:39:15	37.0			23.0	91.0
13:39:30	37.0			21.9	92.0
13:39:45	37.0			22.2	92.0
13:40:00	38.0	63.0	54.0	21.3	95.0
13:40:15	37.0			21.1	92.0
13:40:30	30.0			22.7	92.0
13:40:45	29.0				92.0
13:41:00	30.0			21.1	91.0
13:41:15				20.2	90.0
13:41:30				18.8	91.0
13:41:45					90.0
13:42:00				15.0	89.0
13:42:15					88.0

Incident Resolution

- Department of Surgery, April 11
- “This case ... discussed in the minutes of the March 14 meeting was reevaluated. As per [evidence presented] there was at no time evidence of hypoxia prior to the arrest situation and that there was no evidence of endotracheal tube dislodgement as well. It was [now] felt that **the cause of death was not anesthesia related ...**”

Classic Hemodynamics

Anesthesiology
62:107-114, 1985

Does Perioperative Myocardial Ischemia Lead to Postoperative Myocardial Infarction?

Stephen Slogoff, M.D.,* and Arthur S. Keats, M.D.†

- This classic paper from 1985 utilized the best methods available without computer automation.

Slogoff and Keats, **Methods**

- Observers
- “All data were collected by observers who did not participate in any aspect of patient care. Two nurses and three premedical students were trained to extract discrete information from the patients’ charts, to read oscilloscope tracings, obtain strip recordings, and record collateral information directly from participating surgeons and anesthesiologists.”

Hemodynamics in New York

IARS - 1999

Intraoperative Hemodynamic Predictors of Mortality, Stroke, and Myocardial Infarction After Coronary Artery Bypass Surgery

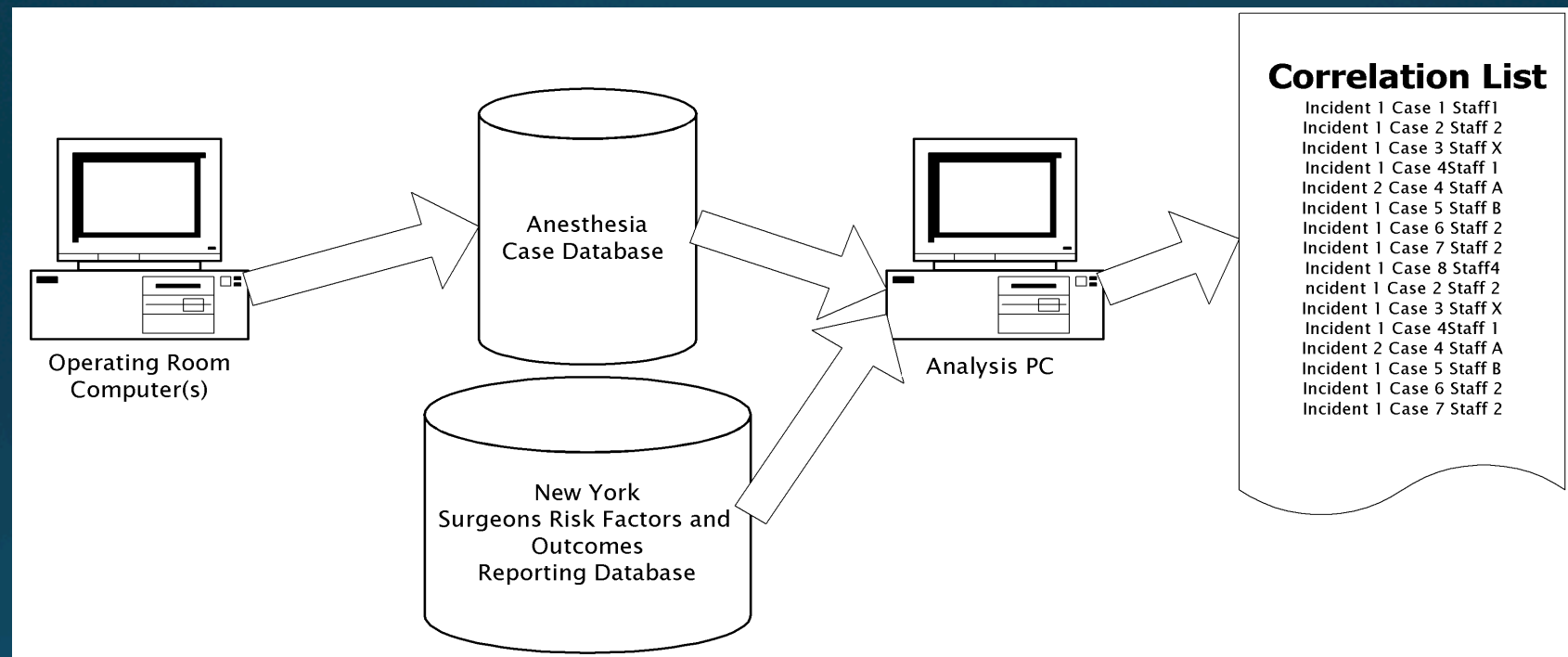
David L. Reich, MD*, Carol A. Bodian, DrPH†, Marina Krol, PhD*, Maxine Kuroda, MPH‡, Todd Osinski, BS*, and Daniel M. Thys, MD‡

- The method is quite different.

Hypothesis

- Are intra-operative physiologic incidents associated with adverse outcome
 - mortality
 - stroke
 - perioperative myocardial infarction
- Combined database data from two large hospitals (both CompuRecord® Users) with New York Cardiac Surgery Outcomes Database

Applied Technology Method



- Data analysis helps you understand what happened and why!

Methods: This is the Point!

- “Intraoperative hemodynamic data were derived from computerized anesthesia records that automatically stored hemodynamic values every 15 s and were used in every CABG procedure at both hospitals (CompuRecord®; Anesthesia recording, Inc., Pittsburgh, PA.)”
- Database files of 2152 patients were used!

From the Discussion Section ... Future Studies

- To continue studying intra-operative incidents, a database is a must.
- The day of hiring observers to write things down with a pen and paper is in the past.

Anesthesiology
1996; 85:977-87
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Lippincott-Raven Publishers

Detection of Intraoperative Incidents by Electronic Scanning of Computerized Anesthesia Records

Comparison with Voluntary Reporting

Kevin V. Sanborn, M.D.,* José Castro, M.D.,† Max Kuroda, M.P.H.,‡ Daniel M. Thys, M.D.§

Medical Center
of Anesthesiology

Anesthesia Quality Review

Date: _____ Anesthesia Care Team: _____

Procedure: Bovine cyst removal

PRE-OPERATIVE:

Complications Related to Patient Preparation	Type of Problem
Invasive monitoring	
Nerve block	
Intravenous Access	
Other	

OPERATIVE AND PACU:

	O.R.	PACU	Post-Op Rounds
Inability to intubate/ventilate			
Dysrhythmia requiring treatment			
New EKG changes			
SaO ₂ < 85 %			
Temperature < 35°C			
Intra-operative change of anesthetic technique			
Dental, ocular, or other tissue trauma			
Other			
Unplanned admission of an outpatient			
New cardiac event (arrhythmia, CHF, MI, ischemia)			
New respiratory event (reintubation, respiratory arrest)			
New neurologic event (peripheral or CNS)			
Other			
	Type of Problem/Injury		
• ADR (allergy, wrong drug/dose/route)			
• Mechanical Failure			

The Study

- (1) Agree on a vocabulary
- (2) Collect voluntary QA information
- (3) Electronically scan automated records
- (4) Compare critical incidents detected

[ADMINISTRATOR] | 01-28-1999 to 02-27-1999 - Quality Assurance Review

File Edit View Reports Search Configuration Help

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Case Number	Service Date	Attending Anes	Patient Name	Medical Record #	QA Completed
McCall, Bonnie Quality Assurance Review					
2Q5JAG10					<input type="checkbox"/>
2Q4M7305					<input type="checkbox"/>
2Q3U7902					<input type="checkbox"/>
2Q327E04					<input type="checkbox"/>
2Q327304.					<input type="checkbox"/>
2Q2AE103					<input type="checkbox"/>

Post-Op QA Indicators	Comment
<input type="checkbox"/> Dysrhythmia requiring transfer to monitored unit	
<input type="checkbox"/> BP more than 200/120 for more than 5 minutes	
<input type="checkbox"/> BP less than 50/40 for less than 5 minutes	
<input type="checkbox"/> SpO2 less than 90% with FiO2 less than 1.0	
<input checked="" type="checkbox"/> Prolonged recovery (> 3 hrs) related to anesthesia	
<input type="checkbox"/> Other post-operative problems	
<input type="checkbox"/> Any other post-operative problems related to post-discharge follow-up?	

☒ Completed Press Space Bar to select/deselect items

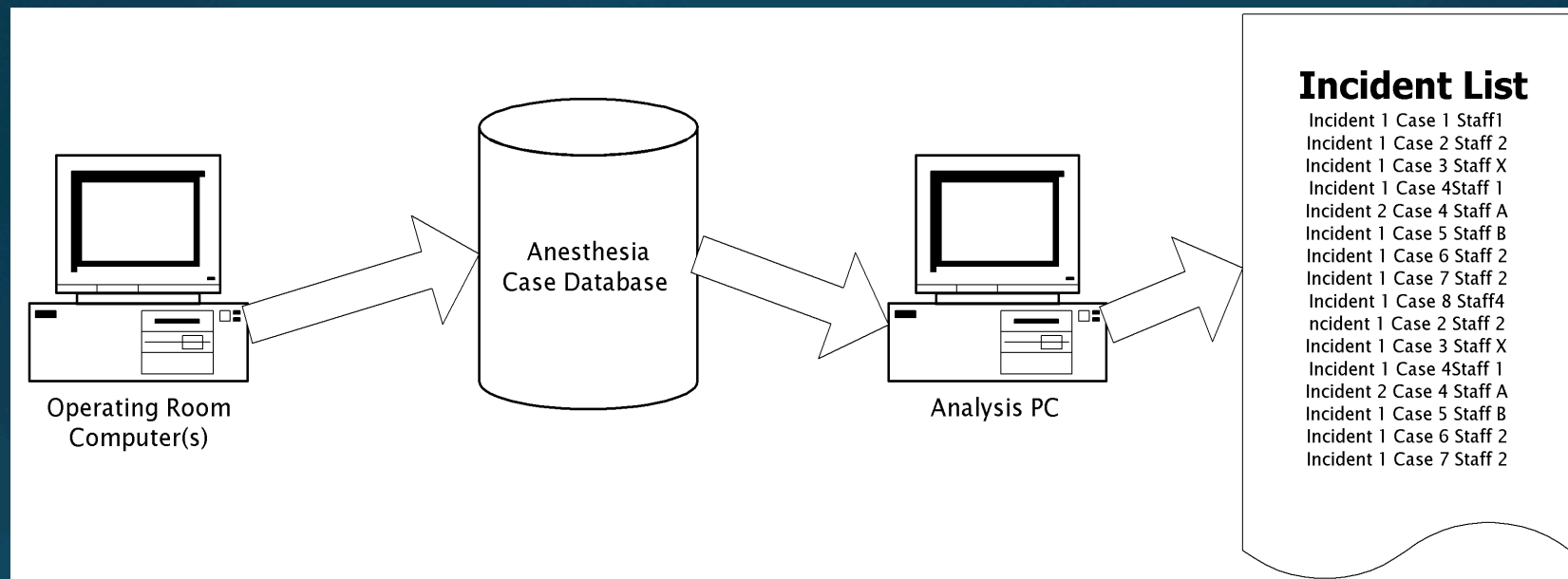
For Help, press F1

NUM 02-27-1999 04:34 PM

The Vocabulary

- Systolic Arterial BP > 195 for at least 10 minutes
- Systolic Arterial BP < 70 for at least 10 minutes
- Heart Rate > 130 for at least 5 minutes
- Heart Rate < 45 for at least 5 minutes
- SpO₂ $< 90\%$ for at least 5 minutes
- Temperature < 34 C for at least 30 minutes.

Scan Database for Incidents



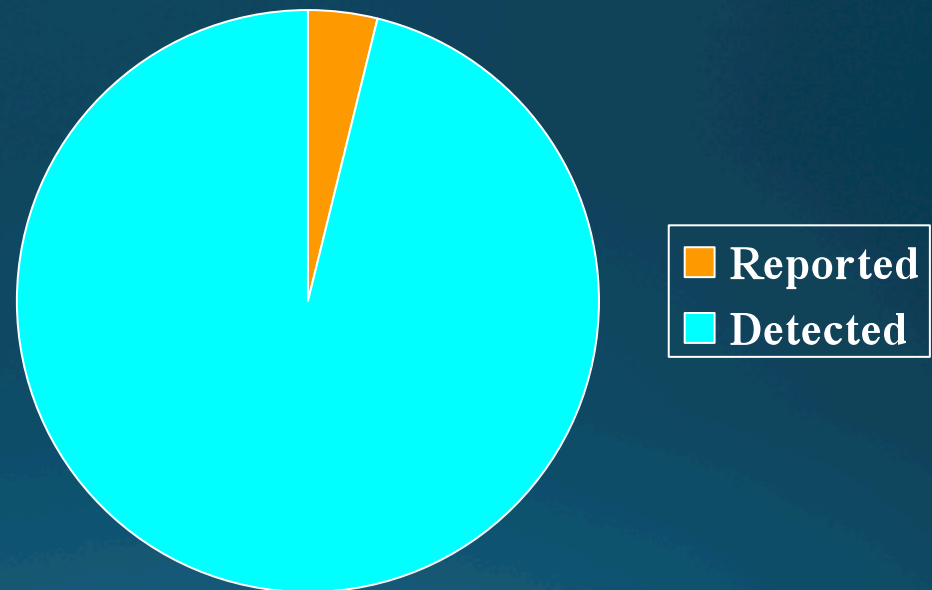
The Data

- 5,454 patients having non-cardiothoracic surgery & anesthesia
- 434 verified intra-operative incidents were found
- 18 (4.1%) were reported voluntarily

The results

- Reported: 18
- Detected: 434
- Correlation: 4.1%

QA Incidents



Statement of Problem

Anesthesiology
68:5-11, 1988

Unexpected Cardiac Arrest during Spinal Anesthesia: A Closed Claims Analysis of Predisposing Factors

Robert A. Caplan, M.D.,* Richard J. Ward, M.D., M.Ed.,† Karen Posner, B.A., M.A.,‡ Frederick W. Cheney, M.D.†

- This 1988 report highlights some of the problems in accident investigation.

Problem Synopsis

- 14 young (~36) & healthy (ASA 1 & 2)
- Arrested unexpectedly during spinal anesthesia with ultimate bad outcome
- A number of additional cases were excluded because there was no data.
- What data there was based on recall of witnesses & hand-kept anesthesia records.
- Did “cyanosis” come first?

Safety includes Prevention

- Cyanosis first, bradycardia first or arrest first?
- Who is susceptible? What do we look out for? Is there a warning sign?
- Is there a pattern?
- Could it be prevented?
- Investigators did a great job with what they had, but better data would have helped.

Technology Applied

A908

ASA ABSTRACTS

TITLE: RISK FACTORS FOR BRADYCARDIA DURING NEURAXIAL ANESTHESIA: MULTIVARIATE ANALYSIS

AUTHOR: J. B. Lesser MD K. V. Sanborn, MD; M. M. Kuroda, MPH; R. Val-skys, MD; G. Silver,

AFFILIATION: St. Luke's Roosevelt Hospital Center, Columbia University College of Physicians and Surgeons, NY, NY USA

Bradycardia Study

- 57,240 cases in on-line computer storage
- 6,663 adult, non-OB spinal or epidural without concomitant general anesthesia
- Vocabulary: Bradycardia
 - Heart rate less than 50
 - Lasted 1 minute or longer
- 720 (10.8%) had at least 1 event

Severity of Bradycardia

Heart Rate	frequency	%
45 -50	686	7.3%
40-45	188	2.8%
35-40	33	0.5%
<35	13	0.2%
720		10.8%

File List View Help



08:50	LR	1000 mL	
08:58	Sinus Bradycardia	SB	
09:07	Fentanyl	100 µg	IV-Bolus
09:08	Sinus Rhythm	SR	
09:15	Ephedrine	10 mg	IV-Bolus
09:15	Atropine	0.5 mg	IV-Bolus

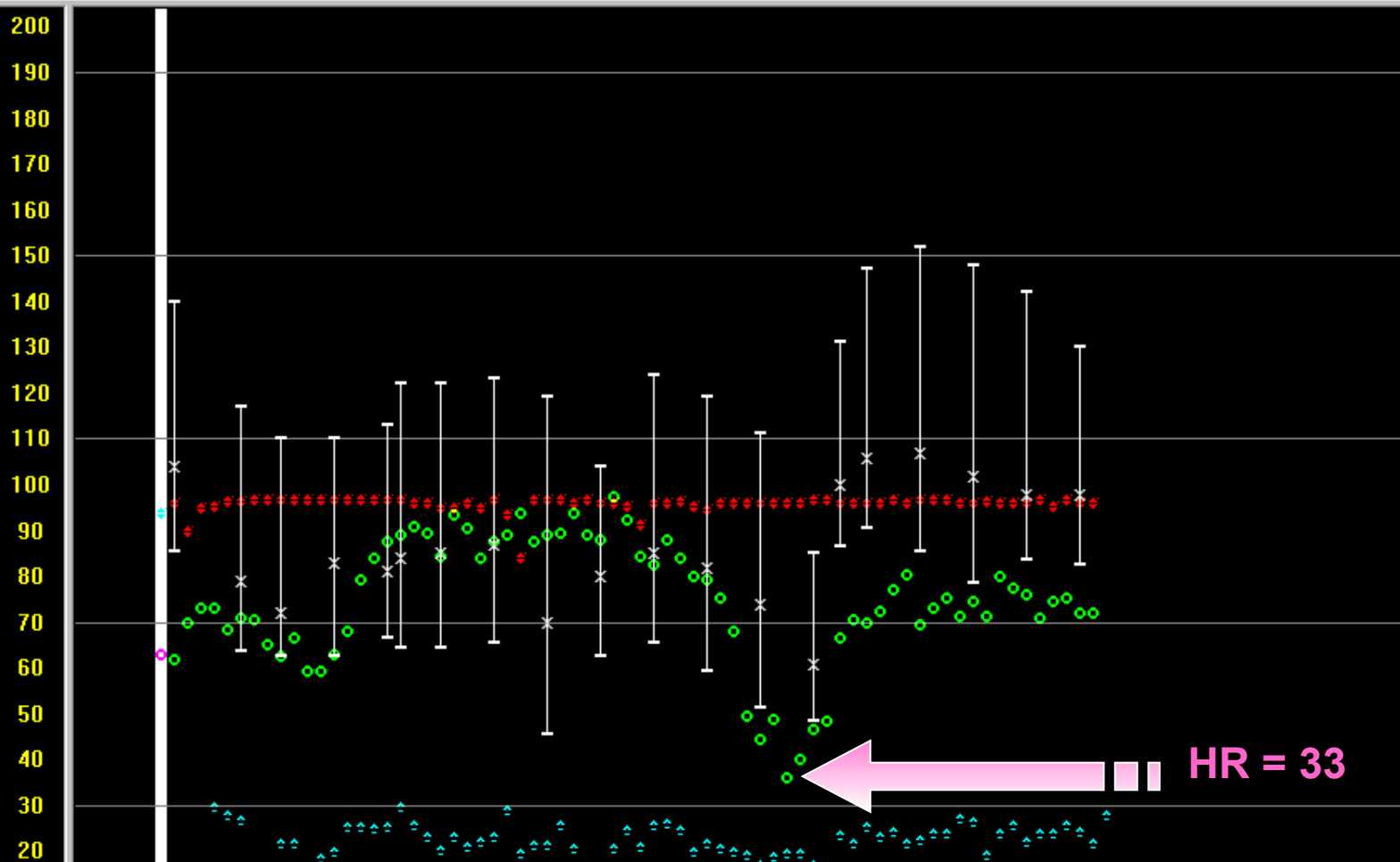
TREATMENT

10-06-1999 08:21:45

Arterial
— / — — v^xHR
63SpO2
95.0FI02
—EtCO2
—RR
—Tgen
—CVP
—elso
—

Prev Set

Next Set



Time	HR ECG	NBP- Sys	NBP- Dias	NBP- Mean	SPO2	CO2- EtCO2	Resp Rate	CO2- insp
9:03:45 AM	75				96	23.8	10	0.13
9:04:00 AM	73				97	25.1	17	0.15
9:04:15 AM	68				97	17.5	17	0.23
9:04:30 AM	51				97	18.6	8	0
9:04:45 AM	68				97	23.2	14	0.02
9:05:00 AM	51				97	9.1	17	0.18
9:05:15 AM	66				97	26.5	12	0.02
9:05:30 AM	48				97	18.9	13	0.1
9:05:45 AM	45				97	20.7	6	0
9:06:00 AM	49				97	11.7	16	0
9:06:15 AM	42	110	53	74	97	8.4	16	0.2
9:06:30 AM	39				97	23.5	7	0.13
9:06:45 AM	47				97	23.5	10	0
9:07:00	Fentanyl, 100 mcg, IV-Bolus							
9:07:00 AM	47				97	18.1	10.5	0.02
9:07:15 AM	41				97	22.9	7.7	0

Time	HR ECG	NBP- Sys	NBP- Dias	NBP- Mean	SPO2	CO2- EtCO2	Resp Rate	CO2- insp
9:07:30 AM	51				97	20.7	19	0.02
9:07:45 AM	60				97	13.5	15	0.66
9:08:00	Sinus Rhythm							
9:08:00 AM	55				97	22.5	15	0.05
9:08:15 AM	39				97	20.7	15	0
9:08:30 AM	32				97	20.7	9	0
9:08:45 AM	33				97	17.8	8	0
9:09:00 AM	38				97	22.9	18	0
9:09:15 AM	53				97	24.5	12	0
9:09:30 AM	42				97	15.8	8	0
9:09:45 AM	36				97	18.1	8	0
9:10:00 AM	34				98	18.1	4	0.1
9:10:15 AM	50	84	50	61	98	17.2	11	0
9:10:30 AM	52				98	17.5	5	0
9:10:45 AM	43				98	21	9	0
9:11:00 AM	51				98	11.5	10	0
9:11:15 AM	54				98	17.8	10	0.15

Time	HR ECG	NBP- Sys	NBP- Dias	NBP- Mean	SPO2	CO2- EtCO2	Resp Rate	CO2- insp
9:11:15 AM	Ephedrine, 10 mg, IV-Bolus							
9:11:15 AM	Atropine, 0.5 mg, IV-Bolus							
9:11:30 AM	42				98	15.8	6	0
9:11:45 AM	46				98	15.8	6	0
9:12:00 AM	56	130	88	100	98	26.2	3	0
9:12:15 AM	49				97	26.5	13	0.18
9:12:30 AM	99				97	23.2	11	0.02
9:12:45 AM	77				97	18.9	11	0.2
9:13:00 AM	70				97	17.2	20	0.2
9:13:15 AM	71				98	22.5	13	0
9:13:30 AM	71				97	29	14	0.41
9:13:45 AM	64				97	22.9	17	0.2
9:14:00 AM	79				97	11.5	19	1.21
9:14:15 AM	70	146	92	106	97	25.8	12	0.15
9:14:30 AM	64				97	30.8	8	0.2
9:14:45 AM	70				97	26.9	11	0

Abstract Conclusions

- In a multivariate analysis two factors only stood out as predicting bradycardia.
 - Bradycardia in the “control” vital sign measurements
 - Male Gender
- New Policy @ St. Luke’s Rosevelt: starting HR < 60 in male patients receives prophylactic I.m. ephedrine.

Our American Dream

- This was an example of the American Dream
- We had a dream, to build a database, a tool for solid clinical research on human patients having anesthesia.
- We are grateful because we were able to grow as people through our experience
 - In medicine
 - In business
- I never did the research I started out to do, but we facilitated solid research done by outstanding people.
- Receiving the Gravenstein Award today is the capstone on a wonderful career.