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Quality Assurance for Automated ICU Temporal Data Management

Pattern Recognition Strategies to Benchmark Automated Physiologic Data Management Systems in Critical Care Venues

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Keywords

Benchmarking, Cardiology, Catheterization Laboratories, Clinical Computer Systems, Clinical Information Systems, Computers, Documentation, Intensive Care Units, ICU, Hospitals, Neonatal, Neonates, NICU, Pattern Recognition, Pediatric Informatics, Testing, Safety Critical Systems, Quality Assurance, Verification, Validation, Visual Processing, Temporal Data, Temporal Patterns, Time Series Analytics.

Abstract

"Meaningful Use" incentives for computerizing clinical healthcare are fostering attempts to automatically archive device-generated, time-series patient data in an "electronic medical record." Proprietary legacy devices plus pre-existing locally developed software systems are being integrated with commercial hospital information systems (HIS), creating many unique and complex patient data management systems.[1-3] Technical quality management of "safety critical" real-time clinical data delivery is an emerging science. Methodologies and tools for quality and cost-effectiveness analytics designed to benchmark data capture are not readily available to physicians. Quality of automated physiologic data in intensive care units (ICU) situations over time is highly variable.

Direct visual screening of large numeric tables looking for intermittent partial failures of proper timing and/or of data arrival in the the target archive (the "electronic chart") is a daunting task. We developed fast, easy and free visual methods to detect data loss in thousands of lines of time stamped, spreadsheet-style vital sign reports. The data originated from ICU monitors used in neonatal and pediatric ICUs. Method validation used data from three different automated charting systems. The visual methods use Excel97™ linear graph "wizards" to visually screen for overall system dysfunction. The wizard's automated "count" functions graph logged time stamps recalled from computer archive files. The graph creates a visually compelling and temporally accurate picture of computer system performance over time. Data absence gaps appear as pattern disruptions everybody sees. This "temporal patterns" graphing utility shows the existence and pinpoints precise timing of data acquisition problems at a glance. The visual pattern is an accurate, time-series overview of system throughput performance.[4]

We tested method generalizability with research sets of neonatal and pediatric critical care vital sign data, automatically acquired by three different bedside monitor/interface/archiving systems in two different hospitals. Each system had unappreciated faults causing significant vital sign data loss from the permanent patient record. Direct visual inspection of physiologic value trend graphs may completely camouflage data gaps if data are plotted on a temporally inaccurate horizontal axis.

Conclusion: Computer systems manage clinical critical care data used by caregivers in real-time to evaluate situations when minutes count, medical details and decimal points matter. Archived

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data may be recalled by clinicians or lawyers for post hoc assessment of clinical problems. Ongoing audits for complete and correct data management by the computer system (benchmarking) are needed. Data quality audits to assure automated critical care data integrity should be routine for critical care clinical information quality assurance.

Introduction

Managing bedside medical information in ICUs is conceptually complex and time-consuming for the care-giving team. In the "paper world" hundreds of serially time-stamped patient data elements were recorded on large folding "flowsheets" ~3 feet long, using a pen. Clerks, not time-pressured doctors and nurses, waded through clunky "ordering" interfaces. Electronic patient clinical data from computerized bedside machines, infusion systems and pharmacy devices were copied by human experts from machine screens and paper labels on fluids or meds onto the 24 hour flow sheets' "boxes" for permanent archiving of the hour-by-hour situation.

The temporally structured, all-in-one-place, paper flowsheet charting methods created a daily "24-hour clock matrix" that contained quick visual prompts for expert rounding clinicians, encompassing hundreds of care variables at a glance.[5-7] Information immediately available visually included where in the day the problem(s) happened, approximately how many physiologic systems were affected, whether the patient has "restabilized" or not, and whether optimization goals for daily LOS data metrics (e.g. weight gain ~20 grams) had been met.

Cross-disciplinary communication between doctors, nurses, respiratory therapists and other technical specialists depended on the bedside visual exam of the patient coupled with shared at-a-glance flowsheet information. Each individual expert considered his own parts in the context of team-based cognition to make minute-by-minute interactive patient care management decisions.[7] A fundamental value of paper methods was that all direct caregivers (the "team") were looking at the same, temporally structured page. Current computer "flow-use sheets" completely fragment this shared "vision" of patients' status.

Temporal patterns of intermittent events charted on flowsheets are easy and natural for human experts to see.[5-7] Humans are much better than computers in processing visual data into meaningful information (*Figure 1*). Humans can often see temporal patterns at a glance that current computers simply cannot extract.[5,10] However, the poorly designed, fragmented "flowsheet" reports that HIS computers generate create "cognitive overload." Poor information displays fragment physiologically interactive critical patient data into poorly designed and medically illogical "department" reports. Fragmented data formats "blind" and frustrate working critical care experts (physicians, nurses, respiratory therapists, and consultants) and leads to errors.[8-11] Hospital-based testing of adult designed systems and devices in neonatal and pediatric sub-populations is limited.

Patho-physiologically incorrect fragmentation of streaming, organ-system related critical care information coupled with an extremely interruptive work environment, leads to mistakes and oversights.[10-12] Computerization for delivering "decision support" is envisioned as a mechanism for quality improvement. For pediatric and infant decision support, developing both the knowledge bases and safe and effective algorithms are Informatics and Computer Science research areas.

Caregivers depend on bedside critical care devices that generate patient and treatment-related clinical data using internal computers. Those computerized devices communicate by several different computer languages through "serial" and/or "network" ports installed in the machines. Industry communication standards don't exist for RS232 serial port messages, usually written in "byte" code. Byte messages are inherently "fast" in DOS systems. Some devices' network ports use TCP/IP (internet) standards, which are processed more slowly in DOS-based machines and are "leaky" (*Figure 1*).[13]

Clinicians need ongoing access to practical benchmarking tests that monitor technical data throughput performance of their hospitals' automated data archiving systems, over time. Because of the national "Meaningful Use" incentives' timelines, hospital administrators are buying and quickly installing commercial hospital information systems, including into critical care units. Many installations currently going live have had little testing, minimal clinical physician input and little planning for how to monitor the quality of patient clinical, as distinguished from financial data.[2,3,14]

Data Integrity Problems Causes: Diagnosis of performance problems with HIT systems only begins when the humans responsible for system management realize that problem(s)

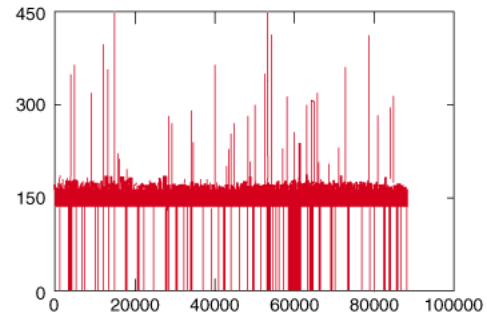

Figure 1. Packet Loss During Internet Transport: Automatic computer archiving of device data is a goal for ICU computerization. Institution-specific Hospital Information Systems (HIS) are being linked with commercial monitors for automated distant archiving. Not all data will arrive. Computer systems using internet protocols to move data are "leaky." Formal testing of TCP/IP throughput time found "packet" loss. The figure "0" indicates non-transport of packets.[13] This figure originally appeared in Dr. Dobb's Journal, May 2001 - www.drdobbs.com. Used here with permission.

impacting patient data integrity and accuracy are occurring.[11] Solutions begin when the hospital or health system managers agree to address the manifest problems. Not all are as simple as a disconnected cable.[11] For example, some commercial monitors and devices report a few data elements only on face-plates, while delivering no matching data to the output ports used for automating "charting." Nonsense alpha-numeric signals may erratically appear from backend ports that are not patient data, but may be medical device error codes (*Figure 2*). Data disappears (*Figures 5-9*).

Clinicians need usable ways to detect whether offsite developers' oversights, programming shortcuts, or "backdoor" technical messages are corrupting the accuracy of a patient's physiologic and treatment data archives. Unrecognized error codes can confound automated systems and the non-developer humans trying to analyze and troubleshoot the devices' puzzling data "corruption." Information about the error signals is sometimes missing from device user manuals. In many cases, the hospital IT system administrators and/or the third-party marketing company that is selling different vendors' FDA-cleared devices also have little engineering insight into the devices' performance issues.

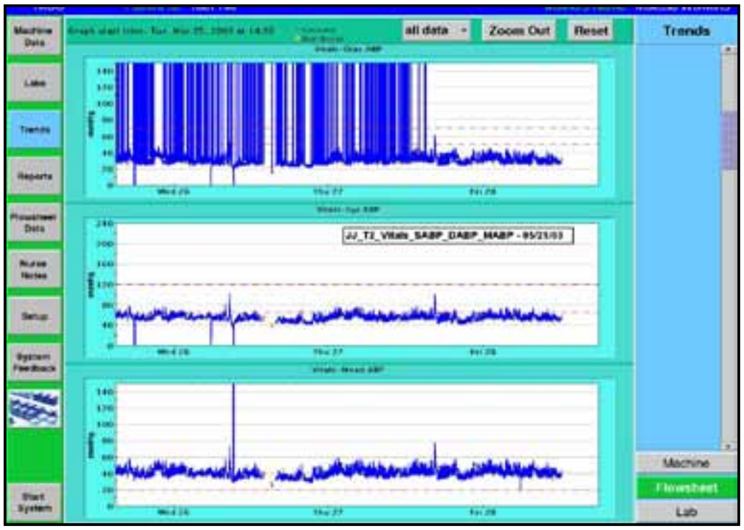

Figure 2: System B; Version 2. Display corruption caused by the "Mean BP = 28" error that was caused by 12-digit number output each time a 27-week premature baby's normal blood pressure hit 28 mmHg. A software patch corrected the problem. Orange dots = nurse charted values. R2 > 0.95 for match with auto chart.

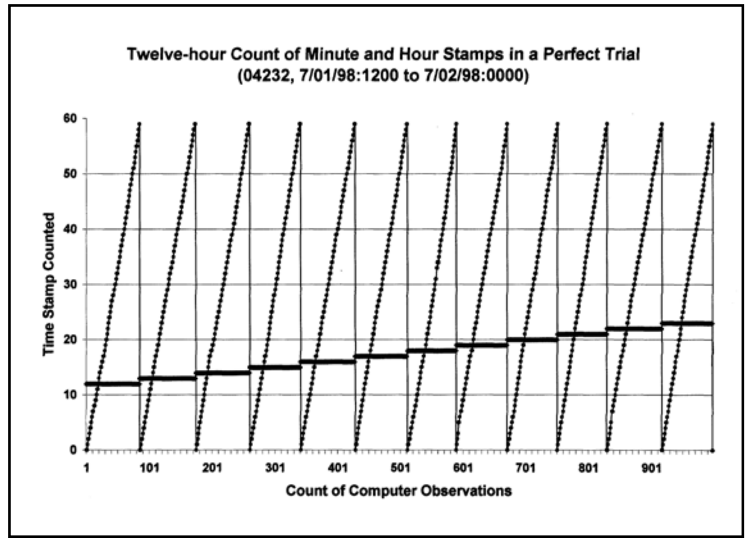

Figure 4: Nearly perfect trace from a near discharge, well preterm infant who had only a single ECG monitor lead. Find the 3 skips in 1000 monitored minutes, fast.

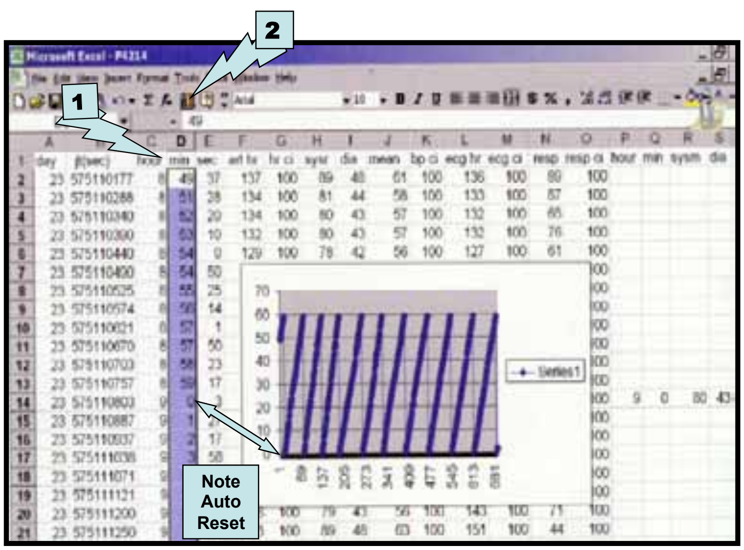

Figure 3: Making The Graph.

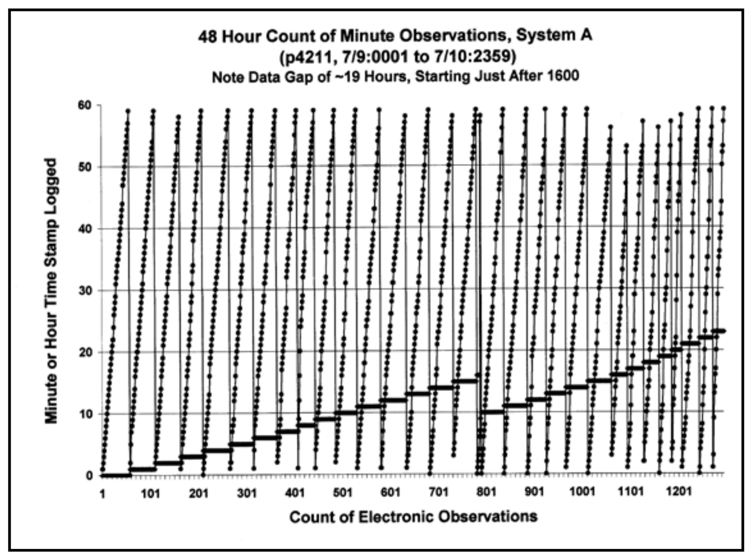

Figure 5: Data disappearance is indicated by the irregular pattern of skips, and by narrowing of the sawtooth pattern as counts of data arriving decrease.

The essential problem is that as linked computer systems' complexity escalates, it becomes more difficult for clinical users to diagnose system malfunctions.[3, 8-10] If clear "system status" feedback about data loss is not delivered visibly to users in clinical real-time (milliseconds for ECMO situations), accidents can happen.[10,11] Currently, vital sign "data disappearance" may be the first symptom of multi-factorial, solvable problems in complex HIS systems' architecture.[2,3,14]

Materials and Methods

We developed and tested a visually-based methodology to pinpoint the start and end time of large system dysfunctions that cause data loss. The utility was designed to help clinicians detect data losses from automated "charting" systems.

We treated the entire automated charting query/response system as a "black box". Using timed data arrival (or not), we were able to create "performance graphics" using the validating computer's time stamp (for data arrival), within Microsoft's Excel 97's automated text file importation, count functions, and graphing 'Wizards". These graphs provide clear system feedback to the clinical users (*Figure 3 - 5*). We assume that all clinical vital sign data are delivered with an associated date/time stamp. Sidebar 1 outlines the three test systems' features. Each system was set to archive one vital sign data point every minute. Estimator calculations of data loss (or gain) over either 3 or 6 hour time segments were determined from the Excel spreadsheets by using, (1) the count of data points as the numerator, and (2) the human-determined count of elapsed minutes as the denominator. Then suspect segments were graphed using the visual method shown in Figure 3.

Test data sets were generated from ASCI download files, that used the Excel™ file import wizard to decompose the comma delimited value fields and the colon delimited (hh:mm:ss) time columns into their component parts, while leaving the mm/dd/yy date column intact (*Figure 1*). Start and end times were precisely set by the experimenter. First, the Excel™ import wizard reorganized thousands of text file rows; then,

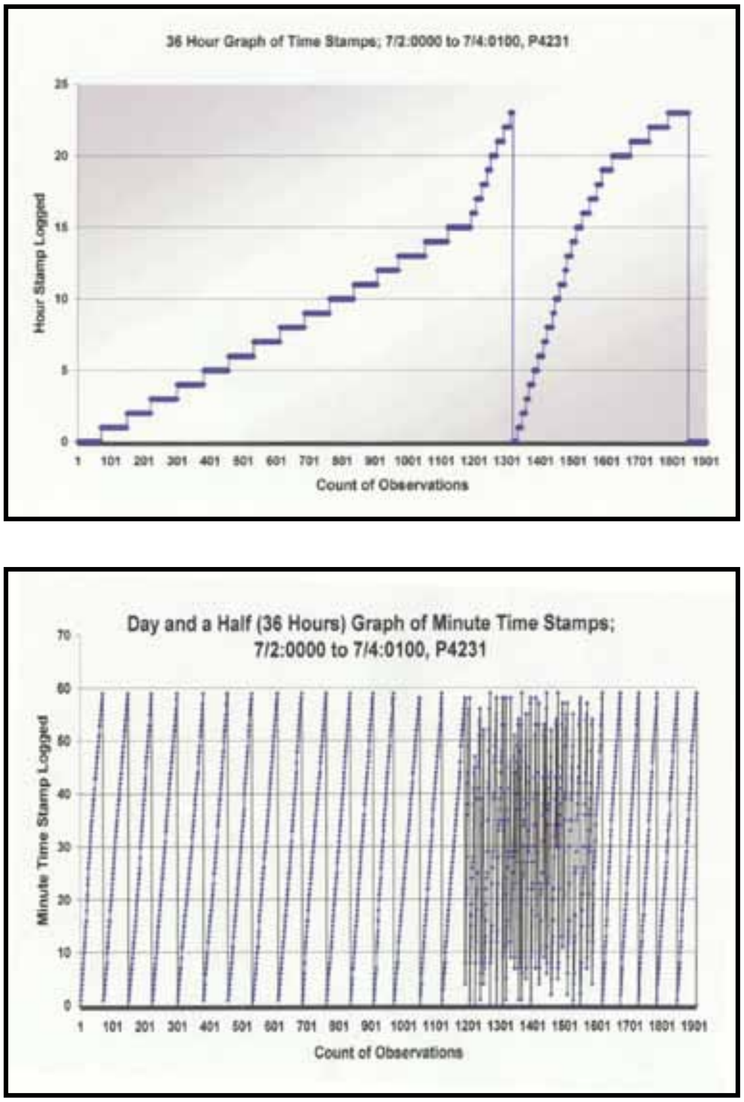

Figure 6. Time Aligned Hour and Minute Graphs of Vital Sign Data Drop-Out That Was Associated With Competing System Server Traffic for Back-Up Archiving (Holiday Weekend).

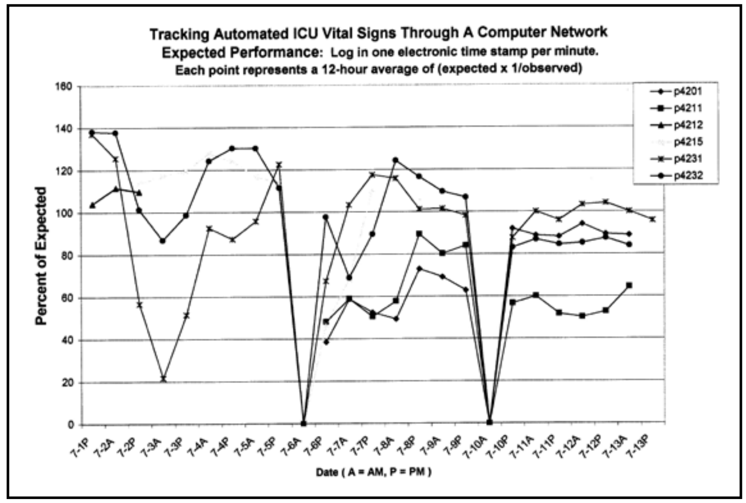

Figure 7: All data transport to archives failed when servers were down somewhere.

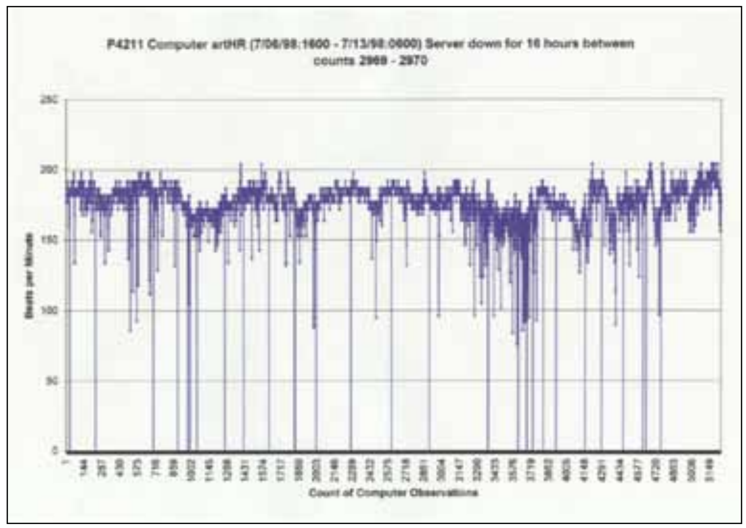

Figure 8: Example of a lost data problem that was difficult to detect from visual inspection of the raw spreadsheet graphs. The lost data were found by using the series of graphing and calculation utilities we created. The sixteen hours of missing data are invisible due to lack of temporal graphics. The barred pattern is caused by the device's internal algorithm to "round to nearest 5."

second, when the single target hour, minute or physiologic value column was highlighted, the linear graphing wizard created the performance graphics (*Figure 3*). The graph itself shows precisely where time stamps disappeared and reappeared because the minute and hour stamps both plot correctly to the y-axis as "count of computer observations", leaving a visually obvious gap in the data matrix (*Figures 4 & 5*). When expected data points are missing, the "saw-tooth" pattern narrows as visible "skips" appear.

System A: Neonatal Intensive Care Unit: Children's Hospital

System A was an experimental distributed system using a vendor-provided automated vital sign archiving program. The querying/receiving server was a high-end multiuser server a mile offsite, linked through an underground hard wired connection. System A's bedside monitors were linked through the vendor's multi-unit interfacing hardware component, physically located outside the intensive care unit, but inside the hospital building. Locally developed software linked the querying computer with the proprietary "partial" interface and with the archiving server.

The Healthcare System server used decision support algorithms to determine whether the signal(s) containing heart rate information originated from an ECG or an arterial pulse trace. Institutional policy gave the pulse-wave signal precedence over the ECG trace for heart rate archiving.

System A Patients were six babies 24 to 37 weeks gestation, weighing 600gm to 3200 gm, enrolled after IRB-approved parental consent. Acuity ranged from critically ill patients, in shock with a massive intraventricular hemorrhage, to a grown premature infant on a heart rate monitor waiting for discharge. The babies' machine-acquired bedside critical care vital sign data had 49,038 rows of timed-stamped vital sign data collected over 12 days.

System B: Freestanding Real-Time Data Management Project; NICU in a Tertiary University Hospital

This project developed critical care bedside data acquisition/archiving workstation that accurately automated real-time data acquisition from different bedside devices to supporting extracorporeal membrane oxygenation (ECMO) data management.[15] ECMO is one of the most in-

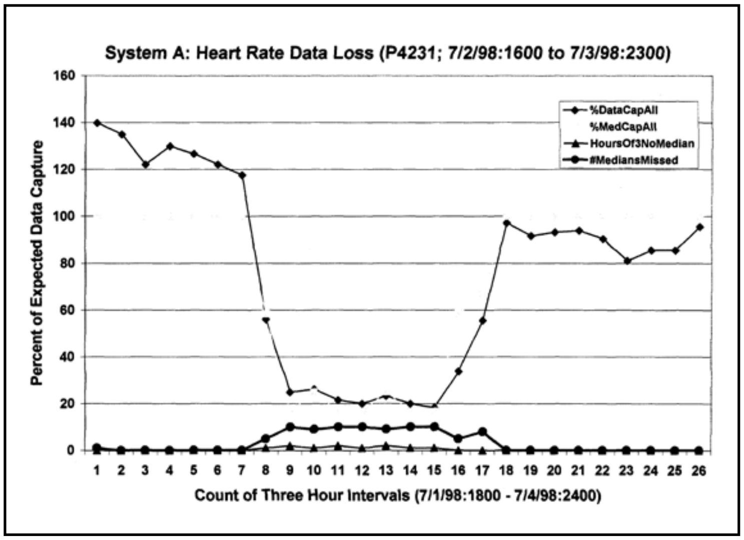

Figure 9: Heart rate data loss in a patient with an excellent baseline data-capture ratio, during a server overload situation.

vasive and complex techniques used in critical care to treat the sickest babies. Our ultimate goal for automatic data acquisition of complex data in clinical real time was to study dynamic changes in neonatal ECMO patients' brain function and blood flow during treatment, especially those related to temporally-simultaneous physiologic and pharmacologic correlates.

The InfoStat Corporation had an engineering graduate student team develop a software system to run on Windows 95©/Office 97© 120 MHz bedside 486PC workstation.[16] With IRB approval, InfoStat was tested in situ during 1996-97 for data accuracy and system speed with 8 near-term potential ECMO patients, each connected using the new interfaces to blood gas monitors, ventilators, physiologic monitors, oxygen saturation and CO_2 monitors, and an online ECMO system flowmeter. Device data was ported to an Access™ database in the bedside machine. The development goal was that vital sign data from each attached machine would update once each minute.

System B Patients were IRB consented neonatal ECMO or pre-ECMO patients; 259 monitored hours were collected over about 12 months.

System C: Children's Hospital PICU

System C had archival data from a hospital project to validate automated vital sign data archiving protocols during a Pediatric Intensive Care Unit (PICU) monitor system installation. These de-identified data were retrospectively reevaluated to test the visual inspection methodology in an older patient population. The PICU data were generated using a third brand of patient monitors, a different locally programmed interface, an older network, and the same central server that managed System A data, three years later. The time-stamped data were up-loaded from a FoxPro spreadsheet and reformatted into Excel97 by IT system management staff. Data transformation errors were possible.

System C was part of a distributed, multiuser health information system that depended on a complex network of proprietary and locally adapted hardware and software for the functionality needed to port the patient data to the target archival database. All systems were hard wired, not wireless.

System C Patients: The de-identified PICU patient data had 321.4 hours of vital sign recordings from 8 different patients.

Results: Data Capture Over Time, or Not?

Each system had unappreciated faults that would create significant vital sign data loss from the permanent patient record. Direct visual inspection of physiologic value trend graphs may completely camouflage data gaps if data are plotted on a temporally inaccurate horizontal axis (*Figure 8*). Data gaps in huge numeric spreadsheet formats are nearly invisible.

Results System A: NICU Automation Attempt (Figures 4-7)

Total failure of patient data archiving occurred over about 47 hours (13%) of the 360 hour patient-connected elapsed time. Data problems included long dropouts, highly variable performance between babies, and clear points where all data capture stopped. Hypothetically, the long data losses were due to server downtime for maintenance.

The long dropouts during days of recording were first detected by statistical disagreements of specific performance measures when calculated in 12 hour segments from the spreadsheets. This "discovery" of very hard-to-see data loss problems conceptually led to the development of the graphic "targeting" utility we report. Numeric averages calculated in 6 or 12 hour blocks can obscure serious transient data loss problems.[17]

Case Discussion

System A's best case patient scenario occurred when only an ECG signal was recorded from the pre-discharge stable baby. For the best baby, data capture by the central system server averaged 101.7% of the expected goal of one sample/minute. Calculated interval data capture values varied from 91.7% to 140% of expected. Irregularities of the timing for data capture ranged from minor to marked. Small data losses were scattered throughout nearly all the record. Some loss segments were as long as 10 - 20 minutes. Pictures of data capture (or not) over time are visually striking and conceptually intriguing (*Figure 6*). Trend graphs of physiological variables (i.e. heart rate) that are shown with "count of observations" on the horizontal scale, rather than a correct time measure, completely obscured major data drop-out, even 16 to 19 hour breaks (*Figure 8*).

The sickest, smallest patient was a 24 week premature in shock from a brain hemorrhage. That baby's computer record captured only 59.9% of the expected goal. This calculation does not include the 16+ hours with no data at all from any patient (*Figure 7*). Some of the most striking failures in System A seemed to be due to precisely definable beginning and end points of some form of processing interference. (*Figure 6*) During the worst losses, some patients did not have enough data captured to archive even the one "Vital Sign" measurement/hour needed to match the archival paper flowsheet standard (*Figure 9*).

Overall System A's "Vital Sign" archiving performance showed that the system as implemented was very unstable and prone to sudden loss of nearly all data for periods of many minutes to hours.

The data losses were probably multi-factorial. The system attempting the vital sign capture was a distributed, multiuser system with no routine data quality check or data arrival documentation methods. Multiple routers managed the data throughput. Technologies for routine, ongoing surveillance of the throughput quality of computer automated critical care clinical data "charting" across distributed network systems are not yet routinely used in many current installations.[11]

System B: Freestanding NICU Bedside Workstation

The monitor-acquired data from "in-situ" system tests had 259 hours of bedside clinical trial data from 8 NICU patients gathered in the mid-1990s. Network problems did not affect this freestanding device system. Problems with local device cables, user-induced impacts (e.g. piling supplies on keyboards), daylight savings time changes, power plug disconnects, and hospital emergency power system down-time tests (at 0300 hours every Monday), did impact the prototype system. The data were reevaluated using the graphic-assisted inspection method. Remediation after the "in-situ use test" reality challenge included adding an automatic software reboot utility, a local backup power pack and a few software redesigns.

System Quality Assessment Descriptors: Derived Table

Patient ID	Study Minutes	"Grade"	# Gaps	Total Gaps Minutes	Obs/Exp%	GapRatio%	TotalErrorCapture%
2204	3738	C	8	206	93	5.5	98.5
2212	4490	F	15	212	93.6	4.7	98.3
2201	1437	C	2	22	98.8	1.5	100.3
8232	1354	C	6	125	2.2	7.7	99.9
42516397	1440	P	0	0	100.1	0	100.1
45377371	1533	P	0	0	100.1	0	100.1
9030306	1315	P	0	0	100.1	0	100.1
P1all2	3975	F	4	161	95.9	4.1	100

Grade: Assigned based on visual inspection of hour and minute graphs. **P** = perfect pattern; **C** = a few flaws, unlikely to impact every one hour data archiving; **F** = gap(s) that would likely have caused failure to archive even a single vital sign/hour.
Gap: Values assigned based on visual inspection of hour and minute graphs. Observed/Expected was calculated from logged minutes and count values. The system was expected to store 1 observation per minute to the data archive.
Gap Ratio% is the total gap length as visually estimated from the minute graphic divided by known "study minutes" for the specific study (Column 2).
TotalErrorCapture% is the sum of **Obs/Exp %** + **GapRatio%**, used as an estimator of the sensitivity and accuracy of the system error detection methods. This value will be >100% if the system is overrunning the target data acquisition timing intervals.

Case Discussion: Data corruption may impact automated vital sign data archiving. Currently, the expert humans using paper flowsheet charting methods tend to employ "intelligent smoothing." This function is delivered by experienced nurses who rarely "Chart" vital signs in the middle of a care episode, a crying fit, or other bedside-induced patient stability disruptions. Automated computer systems do not necessarily differentiate resting from "agitated" data. In bedside testing of the modified System B, we found that nurse charting, whenever it happened, matched the hourly central tendency of the automated trace with an R2 > 0.95 (*Figure 2*).

System C: PICU Data (Table)

For System C analytics, we prospectively graphed the data, then made observational judgments based on a visual analysis grade, compared with the count of gaps, the total gap minutes, and the various gap ratios.[18] This data set had better data capture than the partially vendor designed, partially homegrown system used for the System A trial.

Case Discussion

The visual performance graphic of recurrent 60 minute and/or 24 hour patterns make data drop out instantly obvious by visual inspection. Our visual methods pinpoint data loss in tens of thousands of lines of automated vital sign reports generated by different systems of networked commercial monitors. No training is needed. Data gaps appear as pattern disruptions that everybody can see (*Figures 4-6*). This simple "visual analytics" method holds promise for helping critical care physicians, nurses, and/or local system managers determine whether the computer systems' archives are properly capturing their patients' automated streaming vital sign, ventilator and other time-series device data, or not (*See Sidebar: Streaming Vital Sign Data Quality Audit Checklist*).

New temporal graphics show the overall technical quality of streaming system data, including loss in route from the bedside to the archival database, then back to the bedside for clinical use. Delays of many minutes (even hours) relate to network traffic or server malfunctions and/or local impact problems. Non-TCP/IP streaming, raw temporal data can't wait, it really does simply disappear if it fails to reach the target archive at a timely moment, unless it has a defined "place" to wait, and a software method for inserting it into its' correct time slot when it does arrive, with a logged arrival time, and an audit log to track later access(es). Computerizing all these obvious "specifications" for critical care clinical data management is a high-level, professional software engineering job, not one for a vendor to leave for clinicians. Using TCP/IP systems ramped to millisecond critical care speeds accurately will require technical and workflow redesign for most hospitals.

Why Does "The Data" Disappear?

1) Device Internal Computerization

In each study, some vital sign data did disappear unexpectedly somewhere between the patients' devices and the central (archival) server's download.

Physiologic monitoring machines that are currently used in operating rooms and intensive care units are internally computerized in complex ways. FDA-cleared bedside devices may contain different software algorithms for:
a) analog to digital conversion,
b) "artifact" detection and management,
c) data storage protocols,
d) automatic reconfiguration utilities to keep the particular physiologic trace(s) centered in the space allotted on the screen, and,
e) ways to deal with time stamps and temporal (time-based) redisplay of "trend" information.

The design and technical details of the devices' operational software and processing algorithms may be held as trade secrets by the device manufacturers.[8, 14]

2) Software, Hardware & Network Interactions

Interfaces to physiologic monitors, other medical devices and treatment machines may use several different computer communication strategies. Some hospitals use free-standing, multi-function bedside workstations (System B), that save the collected data locally in 2 places, while also sending it by a wired connection to the institution's Hospital Information System (HIS) archives. In this situation the local interface program will query each designated data source in sequence for the desired data at pre-determined time points. Then the querying computer waits for the response and stores the returned value, with each data element's associated timestamp.

System Summary

Clinical Vital Signs Test Systems

We tested the visual screening methods on three research sets of monitor-generated neonatal and pediatric intensive care vital sign data (931.5 hr) from 3 different ICU monitor, interface, monitoring systems.

- **System A.** A NICU distributed network system that had linked, multi-bed, vendor provided interface hardware, local programming for system link-up, and the querying and archiving computer in a distant building. Six enrolled babies, 27-34 weeks, 49,038 rows of data over 13 days.
- **System B.** Freestanding NICU multi-machine data acquisition/integrating/archiving workstation. Eight ECMO patients, 259.0 monitored hours over about 12 months.
- **System C.** PICU pre-implementation tests of an automated vital sign archiving system. Eight de-identified patients, 321.4 hours over about 18 months.

"Stand-alone" systems can be vulnerable to user-initiated or local environmental impacts. A good stand-alone system will keep all data available for immediate clinical use at the bedside while in the background locally transforming the vital sign values into an HL7 message. HL7 messages can be more consistently transmitted using TCP/IP protocols. However, use of internet technology may drastically slow down data transport and delay data availability at the bedside, while not completely assuring 100% data throughput integrity (*Figure 1*).

When the querying "HIS" computer was far offsite (Systems A and C), routers and network bandwidth considerations complicated temporal synchronization of the query with the response return. When the archival data was routed to yet a third (and fourth, etc) networked computer, via shared routers, overall system complexity increased. When the querying software was run on a multiuser server, peak loads cause an erratic and unpredictable effect on the querying efficiency, and on data archiving (*Figures 4-7*).

Streaming Vital Sign Data: Quality Audit Checklist

Ongoing surveillance may help define whether causes of data disappearance reside in the monitors and/or their proprietary algorithms, or physical and technical situations in the larger "network", and/or in ongoing network/monitor/physical patient/caregiver interactions.[14]

- As a standard of practice, safety critical healthcare environments should use formal post-installation testing in the target population to assure reasonably complete and accurate archiving of vital sign data; overtime, however, that plan is implemented locally.
- Testing should be conducted before "go-live" using real data from the target patient population, then performance should be monitored regularly.
- Surveillance should include nights, weekends, holidays, and times of high "traffic" loads (e.g. change of shift, during epidemics or for scheduled archiving of administrative data).
- All new bedside planned patient care equipment that is intended to send and/or receive raw or networked critical time-series data automatically, should be specifically clinically trialed in target populations' production systems by assessing the arithmetical "capture ratio," the visual performance benchmark tests, derivative indices and formal software testing, as part of new device's routine installation "in situ" validation process.
- To assess outlier technical performance capabilities, monitors all devices for use in neonates, whose data characteristics are very different from adults, should be tested with different kinds and sizes of sick babies, both before, and periodically after the equipment is networked for automatic data posting.
- Repeat testing and continued surveillance of data throughput, over time (benchmarking), as the centralized HIS system evolves should become part of regular "Clinical Systems Quality Assurance."

3) Infant and Child Data "Outliers"

The vital sign data management failures we discovered probably are multi-factorial. Errors and external influences contribute. One cause may relate to unexpected interactions of infant and child data parameters with the various algorithms that manufacturers have installed in their bedside monitors and treatment devices. Adult-designed machines and software applied to infant and child populations may evoke problems. Early in situ tests of System A, recognized the normal premature infant "Diastolic Blood Pressure = 28 mmHg" as an input software message, that evoked a 12 digit error-code output that corrupted the automated vital sign graphic (*Figure 2*). The error was discovered during in situ testing, and corrected in the following software versions.

The non-documentation of "trade secret" software quirks can blind clinical users to problems that may contribute to data disappearance or corruption. Monitors designed, architected and tuned for adults need performance testing and perhaps modifications before going live in complex, multi-device pediatric and neonatal critical care environments. When devices port data to a hospital information system (HIS) either locally developed or purchased over time, from different vendors, also without child-tuning, undocumented sources of potential error may aggregate, unresolved, and perhaps unseen by the bedside clinicians.

In the installation configurations examined, all three systems were found unready to perform as developers and users hoped.

4) Faulty Feedback to Critical Care HIS and Medical Device Users

System A and C monitors did report faceplate display values that bedside caregivers recorded hourly on paper flowsheets, even when the backend data acquisition totally failed to log a single point/hour. System A had no feedback to the bedside caregivers that errors and omissions in data archiving were occurring. If System B failed to update, the screen time maintained the previous value and the header line turned red. However, the details were easy to miss when glancing quickly at the display from a distance. Red is a poor alerting color because 10% of men are color blind and don't know it. In dimly lit environments, red can visually fade into black shadows/backgrounds. Sometimes even "crashes" that prevent data archiving may be invisible to the user, if the visual integrity of the physiologic data stream is being assessed using a non-time proportionate horizontal axis (*Figure 8*).

Historically, post-hoc discovery of data problems relating to errors and disappearances of data values were reported by a European group attempting to use a very well-regarded production system for clinical neonatal intensive care.[19] Interestingly, the problems the European group experienced during actual use of the patient data system in a working NICU clinical environment differed markedly from descriptions of the same system in an adult venue in the same era.[20] Testing and quality surveillance over time is needed to assure that system function meets "safety critical" patient care specifications.[14] Archiving quality also depends on having temporal database designs in commercial HIS products that can accurately accept multiple simultaneous streams of time-stamped monitoring, ventilator, oximeters, infusion pumps, care and site-specific ancillary data.

5) Poor Designs for Temporal Reasoning for Decision Support in Medicine

When ICU caregivers' situation awareness depends on recall of computerized vital sign data from non real-time HIS systems for making fast-paced critical care management decisions, and for automated alerting and decision support functions, it is unknown what type of error message "the system" should be able to return to signal missing and/or corrupted data. Attention to "temporal reasoning based alerting" for healthcare applications in 2011 is just beginning to become a recognized research area. Automating temporal reasoning to support healthcare clinical decision making is now a hot topic research area.[6, 21]

Conclusion

Data accuracy and integrity problems inherent in automated clinical systems must be discovered before they can be analyzed and solved. If the discovery is weeks to years after the fact, the system, its software and documentation may have changed so greatly that little useful diagnostic information can be discovered by any means.

Clinicians can access near real-time visual inspection of overall system performance using the easy, rapid methods we report. The graphic visualizations can help show caregivers the unexpected system performance problems that corrupt data archiving. Prompt detection will facilitate problem(s) correction while system installation teams or sub-system consultants are still available to find and fix the causes of "disappearing" streaming, time-series vital sign data.

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Global Neonatology Today Monthly Column - Achieving Millennium Development Goals (MDGs)

By Dharmapuri Vidyasagar, MD, FAAP, FCCM

We cannot achieve the United Nations Millennium Development Goals (MDGs) through advancements in medical science alone. We need to increase specific knowledge about, and awareness of health issues among the general public. This is more relevant in low income and resource poor countries. It is also a cost effective way to improve the overall health of a country's citizenry. This is the fundamental precept of public health. How do we achieve this goal? Through education; health education can be realized through increasing knowledge about personal health, but also increasing awareness of citizens' rights to seek health care in their society. This is the focus of the organization, The People´s Health Movement (PHM) - www.phmovement.org.

PHM is a 25-year-old organization calling for the revitalization of Alama-Ata declaration "Health for All by 2000" - www.phmovement.org/en/node/867. The efforts are made at grassroot level in all countries through networking with multiple health related organizations in different countries. Its vision declares "Equity, ecologically-sustainable development and peace are at the heart of our vision of a better world - a world in which a healthy life for all is a reality; a world that respects, appreciates and celebrates all life and diversity; a world that enables the flowering of people's talents and abilities to enrich each other; a world in which people's voices guide the decisions that shape our lives...." The organization has created a document, *The Assessment of the Right to Health and Health Care at the Country Level: A People's Health Movement Guide*, which details how to assess the health care delivery system in a country.

There are five steps to assess the denial of the *right to health* in a country. The five key questions this assessment asks are:

1. What are your government's commitments?
2. Are your government's policies appropriate to fulfill these obligations?
3. Is the health system of your country adequately implementing interventions to realize the right to health and health care for all?
4. Does the health status of different social groups and the population as a whole reflect a progression in their right to health and health care?
5. What does the denial or fulfillment of the Right to Health in your country mean in practice?

These questions lead to the next five steps to be taken up by the organization committed to health promotion in their country.

- **STEP I.** Assesses government's commitments.
- **STEP II.** Assess if government's policies are appropriate to fulfill these obligations.
- **STEP III.** Ask if the health system of the country is adequately implementing interventions to realize the right to health and health care for all
- **STEP IV.** Assess the health status of different social groups and the population as a whole reflects a progression in their right to health and health care?
- **STEP V.** Evaluate what the denial or fulfillment of the *Right to Health* in the country means in practice?

The People's Health Movement guide is worthwhile reading for all those interested in promoting MDGs by 2015.

For details please go to: www.phmovement.org/en/campaigns/145/page

"The Clock is Ticking!"

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