

Vital Sync System™ Test Bed {Entire Care Unit} Installation

[Hospital Name; Unit Name]

Cost Effectiveness Demonstration Project: Concept Outline

Concept Summary (~3000 words)

Draft for ONC Implementation Workgroup Hearing : January 10-11, 2011

**Possible Title: "Automated Clinical Quality Management for Cost Containment...."
Or..... "**

Symbols Used: () **References and (parenthetical) English use**
 [] **Means needs list box, for discrete concepts**
 { } **Means computerized logical design needed**

Demonstration Project Proposal:

Vital Sync System™ Testbed Installation

"Automated Clinical Data Management for Quality Assurance and Resource Optimization"

Funding Possibilities:

- 1) Institutional or Research Grant to UF, under ARRA/HITEC, Follow-On Federal Program**
- 2) Company grant or contract by Small Business Association or AHRQ**
- 3) Contract: (Military, Corporate, Veterans Administration, Government Clinical Patient Records Projects)**
- 4) Other:**
 - a) Research Grants - subject matter based (e.g. Cardiology)**
 - b) Private funding, Foundations, March of Dimes (maybe as a "Nationally Featured" Premature Infant Care Improvement Effort)**
 - c) Osmond Telethon Funding**
 - d) Venture Capital "Refunding" (Local Investors may be available)**
 - e) Pot of Gold at the End of the Rainbow**

Prospectus:

The United States' federal government mandated a national effort to computerize healthcare in a very short time. Generous funding of \$44 billion was allocated via hundreds of different programs and revenue streams, already running. Inpatient settings currently have no product on the market except the Vital Sync System™ that is technically capable of automatically delivering comprehensive, accurate, time-stamped and time-integrated, patient-related clinical critical care data to the bedside clinicians. Simultaneously the system delivers data via HL7 interfaces in the background to inform the "Meaningful Use" indicators.

The Vital Sync System™ is designed from the operating system to the user interface for the specified function of automatically acquiring and accurately delivering, receiving and correctly back-posting temporal (time-stamped) critical care data at the bedside. Each individual Vital Sync™ device contains its' own data storage, locally backed-up by a very near-site, mirrored, fail-over Vital Sync System Server™ server, physically in each critical care unit. This architecture delivers a fail-over system that replicates all bedside data each minute, between the unit-level server and its attached bedside devices.

The Vital Sync System™ is the only FDA-cleared HIS system on the market that is incarnated and certified as a critical care device designed for roll-in installation at bedsides. The system is integrated into the hospital information system using push-buttons for configuration customization. In the background, the fully implemented, multi-tasking Vital Sync System™ seeks updated laboratory information, communicates with ADT about patient name, location and other status changes. Reports graph numeric parameters automatically on zoomable touchscreens that can present weeks of overview data visually to caregivers. Overviews can be instantly expanded from weeks to minute by minute views simply by touching the screen and sliding a finger over the graph.

Vital Sync Systems™ aggregated data can be parsed per local policy, reformatted for permanent storage in archives, and/or transmitted by HIPPA-mandated communication standards to national data warehouses that are being developed under the \$44 billion ARRA "Meaningful Use" funding.

Secure, "always up" systems are mandatory for safety critical environments. Critical Care Units in hospitals are safety critical environments. Current vendors of hospital information systems cannot assure 100% up time of their products. When the Vital Sync System™ is installed in a critical care unit, with its unit-level server, downtime of the hospital network or of any bedside device, or of the unit level server, will result in loss of only a minute of data. Data collection continues on back-up power so critical caregivers can continue work without loss of either automated charting, or of bedside review of previously collected patient data (i.e. from laboratories). Automated data collection continues, because device data acquisition using the Vital Sync System™ does not depend on the hospital's network integrity for constant up time. The national focus is to improve quality measures, using "certified" information technology systems. Inpatient critical care situations need quality improvement in data management technology. Vital Sync System™, "certified" by the FDA, and is UL Certified for bedside critical care patient use.

Dream of Paperless Intensive Care Units: The Future Has Arrived.

Vital Sync System's™ Concept Space

Hospital information systems (HIS) have core software architectures designed in the 1970s through the early 1990s to support sitting, 40-hour-work-week, secretarial workflow. The flat-file format design standards of the era, variably modified, now constitute the core software architecture of nearly all commercial HIS products. Commercial products are difficult to install effectively into complex inpatient environments. Many attempts have either failed outright, or so complexly destabilized clinical care team workflow that positive outcomes are difficult to demonstrate. Reports of deep-seated socio-technical difficulties permeate the informatics literature and professional list serves (1-6).

The Vital Sync System™ is an FDA cleared, computerized "Medical Device" designed to deliver automated data management support minute-by-minute at the patient bedside to facilitate precise care by expert clinicians. The device acquires and charts all possible, computer-generated critical care patient data elements. The Vital Sync™ device runs on a standards compliant, secure, real-time platform that automatically integrates clinical data (i.e. labs), with physiologic patient data from computerized machines (vital signs, ventilators, monitors, oximeters, diagnostic and treatment machines), with clinician entered notes including nursing, physician, social work and physical therapy notes' data.

The Vital Sync™ user interface is intuitive and easily navigated. No function is more than 2 clicks from all other functions. The Vital Sync™ bedside machine continues entering data from connected machines, no matter what is going on with the patient, or with the clinical nurses and doctors, or in the larger hospital information system. External crashes don't matter to a battery powered Vital Sync™.

All clinical Vital Sync™ data are aggregated along a precise, minute by minute timeline. Temporal ordering of fast moving events, automatically captured from monitors and machines is visually graphed in real time to show simultaneous interactions visually. The trend data are easy to explore retrospectively at the bedside using Vital Sync's zooming, drag and drop, trend graphing utilities that support bedside clinical situation monitoring for change-point decision making. Nursing Notes are entered using a checkbox driven, user interface that makes structured data entry easy and fast, without error-prone typing or parsing long pick lists. Data presentation choices are made by users who can quickly change views from visual trends to numeric spreadsheets, and who create readable reports via push buttons.

Mission Statement:

Deliver the Vital Sync System™ conveniently and unobtrusively to front-end clinicians at Intensive Care patients' bedsides. Track human systems and financial change at the hospital's backend, using statistical process and continuous quality improvement methods. Evaluate whether better informed critical care nurses and doctors deliver better, more efficient and effective care (7).

Current Business Situation:

The United States Government allocated \$44 billion over 5 years (2011 - 2015) to support rapid computerization of the clinical components of healthcare delivery. Hospitals and the hundreds of thousands of critical care beds they contain are included in the target population. The federal challenge to get healthcare computerized quickly, starting FY2011 was financially incentivized. The "Meaningful Use" incentive challenge includes payment to out-patient physicians, hospitals that include inpatient critical care workspaces, but excludes inpatient clinicians (8). Federal financial penalties begin after 2015 for physicians and hospitals that are not using clinical computerization meaningfully.

Opportunity Knocks: The National Health IT Situation

A major need exists for advanced computer system design that can adequately support critical care workspaces. Software architecture redesign from the operating system to the user interface has produced a robust, real-time data integrating, secure, healthcare standards compliant, interoperability platform for Hospital Information Systems (HIS). The Vital Sync System's integrating platform automatically integrates device-generated data with all other clinically relevant, time-stamped, HL7 compliant components of the larger "Hospital Information System". Nurses and doctors and nurses no longer must type to transfer data from one computer to another. Customized installation and training time is measured in days, not months, or years.

Vital Sync's decision support starts with vastly improved bedside data acquisition that is returned immediately to bedside caregivers as real time, visually integrated, zoomable trends. Critical Care physicians universally understand the value, with the very first encounter with the zooming trends on the touchscreen; the critical docs "get it", and they "want it". Nobody has to explain the clinical value of the temporally streaming trend views of pathophysiologic data to a criticalist who sees the running Vital Sync System™ at a bedside for the first time.

Clinical Workflow in critical care units is often extremely-fast paced, because the care population involves complex patients who are very critically ill with multi-system organ failures of variable causes. Patients range from 500 gram 23 week premature infants to 400 kg, morbidly obese, elderly cardiac and trauma patients. Critical care workflow is team-based, multi-tasking, and often requires second-by-second decision-making by clinical experts using only the data available at that critical moment.

Technical Situation:

Real-time record keeping is a constant challenge in critical care situations (9,10). Clinicians use folded paper flowsheets to collect ICU bedside data into temporal, operational, condition-related and manageable "chunks". The wide formats (6 to 8 feet) of the paper flowsheets time-align key clinical elements from different data subsets (vital signs, respiratory, fluids, medications, care episodes). This format facilitates quick situation overview of multi-system problems by bedside clinicians. The paper flowsheets' hourly charting spaces accommodate moderately frequent caregiver observations. However, for minute-based critical care decision

making, flowsheets limit manageable data density. Hourly data are usually uninformative to bedside caregivers dealing with minute-by-minute patient changes. Minute by minute retrospective case situation reviews, facilitated by Vital Sync's™ zooming trends are extremely informative for facilitating intelligent decision making in near real time by bedside clinicians, and for post-hoc quality assurance reviews. (9,11)

"Flowsheets" both paper, and those "computerized" by typing data from one computer to another, require that caregivers physically use their hands, either to write data from machine screens into small boxes, or to type the screen data into documentary hospital information system "charting" utilities. Care documentation requirements continuously escalate, often in response to external demands for clerk and billing justification services, not for improving or communicating clinical care (10). Both paper and keyboard charting methods have inherent risks that can impact overall system processes' and outcomes' quality (12). Keyboards in critical care units are vectors for nosocomial infection (13). Computer use by caregivers in critical care environments virtually always distracts caregivers from the patient, the family and the overall ICU situation awareness. (1-3)

Typing-based data entry systems are very unsupportive of fast-paced critical care unit work, especially in venues where physicians and nurses need their hands to deliver care. Typing slows many critical caregivers, as do the multiple "logons" and "re-logons" required for users to recover and finish their work, after interruptions (1,2). The problematic data entry aspect of computerization needs much improvement to rapidly align with the national effort "to get healthcare computerized". Data entry and delay problems contribute to many unforeseen consequences in critical, real-time care delivery venues. (3,14)

Risks & Risk Management:

Identified risks of both paper and all computerized charting methods available to date include illegibility and/or typographical errors, inability to accurately capture the timing, magnitude, and associated interacting pathophysiologic effects of most interventions, and very frequent lack of timely offsite ancillary information at the bedside. Fragmented clinical data presentation impacts clinicians' ability to mentally integrate multi-source, temporally streaming (time-series) data when they are attempting to diagnose all the contributing causes of acute destabilization episodes.

Paper flowsheet charting once an hour creates wide numeric charts with long columns of tiny scribbled numbers that are possible to misinterpret on quick inspection. Sometimes major destabilization events are invisible in the columns of numbers, even in retrospect. Important destabilization episodes can escape cognitive detection in real time. Most overlooked episodes that are missed using grid-box charting become immediately obvious, in clear association with other physiologic changes, when visual trend graphics made post-hoc from the flowsheet data. The hourly charting interval may completely obscure very serious episodes that occur over minutes.

Use of the Vital Sync System™ by researchers and early adopter physicians shows that complications of care, and sub-optimal patient responses to customary care are often

unrecognized in real-time with current data management methods (11,15,16). When hourly charting methods are visually compared to the minute by minute automated data acquisition and "charting" methods delivered by the Vital Sync System™, destabilization episodes and associated physiologic systems' interactions become visually obvious.

Early Detection of New Patient Problems

Complex situations like internal bleeding, life-threatening electrolyte imbalance, septic or traumatic shock, rapidly worsening pulmonary status, and acute onset of infection or ischemic complications, are prime targets for improving care and patient outcomes. "Trigger-based" computerized decision support for episode detection, alerting and advisement utilities were added to the Vital Sync™ applications portfolio in 2010 (17). The core capabilities can be expanded to include more complex conditions.

The National Mandate: Quality Management for Improved Outcomes.

Business Case for the Vital Sync System™

Critical Care Units of all types are very expensive to build, manage and maintain. The national effort to improve healthcare delivery, manage costs, and improve general population health has now reached the end of the first funding year since the beginning of the \$44 billion incentive "Health Information Technology for Economic and Clinical Health Act" ("HITECH") program funded in late 2009, as part of the American Recovery and Reinvestment Act (ARRA) of February 2009 (8). The program is scheduled to begin paying incentives in 2011 to physicians and hospitals for implementing, and meaningfully using, computerized information systems in clinical healthcare venues. Staged eligibility processes will occur over the 2011 fiscal year (8).

Most current hospital information systems (HIS) have "old" installed core software platforms, that were conceptually designed for the physical environment and workflow of the traditional one-on-one, "Dr. Marcus Welby" model of healthcare delivery. That cognitive and computer software design model is 30-40 years out of date. The Marcus Welby workflow model has little relevance to today's major unmet need for much more flexible and faster computer systems to support the team-based clinical care delivery work processes and workflows that are now common in both inpatient and, increasingly, in ambulatory venues. Cross-discipline clinical teamwork, in real time, is the standard of practice in nearly all of today's critical care units.

The Health Information Technology Industry's preparations have been delayed in adjusting their existing products to help their contracted customers meet the new federal reporting demands by federal delay in accrediting "certifying" agencies. Final "Meaningful Use" criteria were published on July 13, 2010; three Temporary "Certification Vendors" were named on July 28, 2010 (18). The 2011 fiscal year started on October 1, 2010. Time to respond with new software development is technically inadequate, so criteria were lowered in the final rule from 80% to 20% for the specifications needed to qualify for 2011 financial incentives, and an attestation modality was added.

To date, very little Human Factors Engineering work has been focused on the complex needs of multi-tasking physician and nursing critical caregivers for time-saving help with data entry and integration in real-time. The clunky, inappropriately designed computers that critical caregivers currently must use are always perceived as "slow" (4,14). Better system design is essential to ensure patient safety, to deliver improved outcomes and to comply with increasingly demanding "Meaningful Use" reporting. (4,5)

Nearly all commercial software designs in existing Hospital Information System have three fatal flaws for critical care venues:

1) They need for hands-on critical caregivers to type information from one computer (the bedside devices) into a different "device", i.e. the HIS computer(s).

Comment: It is extremely cost ineffective for surgeons, criticalists, interventionists, and critical care nurses to use their valuable hands to type. Some surgeons can bill out thousands of dollars an hour. The supporting scrub, post-op and critical care nurses can be paid \$35-\$50⁺ / hour. Good clerk-typists earn about \$12.50/hour.

2) They fragment critical care physiologic systems' information into cognitively incomplete grid-box reports on space-limited screens or 8.5 x 11" paper print-outs.

Comment: The clunky methodology for producing reports in current HIS systems presents a time-consuming, mal-aligned, non-real time picture of the patient's interacting problems. This fact set, coupled with the disappearance of the multi-system, temporally aligned, physiologically integrating paper flowsheets, frustrates and "blinds" experienced critical care clinical decision makers. The current mal-aligned situation leads to oversights and potentially avoidable errors in inpatient venues, especially when many patients are destabilizing or being admitted, simultaneously (4,19,20).

3) They are technically incapable of adequately time-stamping multi-source, minute by minute data arrival from machines, other bedside computers, laboratory computers, and ADT system. Missing key data often include drug/fluid infusions' start and stop times, team-based care actions and patient-caregiver-family interactions.

Comment: Many caregiver interactions occur simultaneously, because nearly all critical care experts habitually multitask while working in teams, which reflects experts' cognitive processing strategies (4, 21). Clinical experts' multi-tasking mindsets are valuable for team-based, coordinated performance in life or death situations. Their clinical computer systems rarely support clinical multi-tasking teamwork effectively (5,21,22,23).

These facts-of-life in ICUs in 2010 lead to significant difficulty for delivering the hoped-for "clinical decision support" to caregivers, in a timely, clinically effective and cost-saving fashion. Virtually all existing commercial systems do not support critical care workflow or data flow management adequately.

Proof of Concept: Vital Sync System™ Whole Unit Testbed Installation:

Vital Sync™ has solved the critical care clinicians' cognitive and practical needs for immediate bedside access to streaming, real-time, integrated complex systems data. This real-time physiological data management machine is a new type of computerized medical device. Vital Sync™ produces accurate integration of real-time patient care data which facilitates very early detection of new complications. Vital Sync™ supports very fine tuning of the combination of pharmacological and physical support needed to preserve brains and maximize intact outcomes for unstable, critically ill patients of all ages, but especially for neonates (11, 24).

Neonatal critical illnesses, while life-threatening, are often temporary. Many neonatal critical illnesses are compatible with totally intact survival, if many different complications of immaturity can be avoided, or treated immediately and effectively while stabilizing and preserving cerebral blood flow. The majority of critically ill infants ultimately survive. Today, more than 90% of all survivors (born at 24 to 36 weeks) are sufficiently intact that they have a long and healthy life ahead. The intact salvage of very critically ill infants produces a high "Quality of Adjusted Life Years" (QALY) calculation - a common financial quality assessment metric for calculating "return on investment" (25).

Clear, automatic visual delivery to the patient's bedside in clinical real-time of accurate, timely, physiologically integrated, multi-source clinical information may improve the early recognition and treatment of deteriorations, may guide more effective product usage, decrease wastage, minimize clinical staff data entry time and improve overall patient care satisfaction.

The expected improvements, considered together, may return far more effective system quality and financial performance information than previous strategies. Key cost indicators would be shorter length of stay, fewer unmitigated complications, lower overall hospital base costs and improved capture of needed meaningful use indicators. All are important financial considerations for healthcare environments constrained by capitated financing models.

Demonstration Testbed Project: 2011

Demonstrating that the Vital Sync System™ can indeed be rapidly rolled out for use at each bed in the test (N)ICU, and can be quickly and effectively incorporated into the ICU patient data management workflow with improvement in cost and quality indicators is a final key step to major market acceptance.

Vital Sync System™ is designed for a major healthcare market that has a near-total vacuum for robust systems capable of automating critical care data management. The new national mandates have created a time of great need for caregivers, and for hospitals. The national situation creates a very opportune moment for Vital Sync's™ contribution to HIT history. A key next step, going forward, is for the Vital Sync System™ to demonstrate unit-based improvement in clinical and process-based "productivity" measures of all types, including caregiver, patient and family satisfaction.

Ideally, the best test situation would be to find two approximately "same stage" critical care units, whose host hospital(s) is (are) willing to work with the Vital Sync™ team to install Vital Sync™ first into one, and not the other. Then track multivariate outcomes measures of both units for outcomes' change analysis, for about 6 months. An interesting project design would be to then take away the devices from one unit, and install the machines in the other.....and evaluate the consequences. Reports are sure to follow, probably from distressed caregivers whose Vital Sync's just disappeared, leading the way.

The proposed test bed installation demonstration will create facts to inform valid market decision-making about the short, mid, and long-term scope of Vital Sync System's™ currently wide-open market.

Respectfully Submitted,

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