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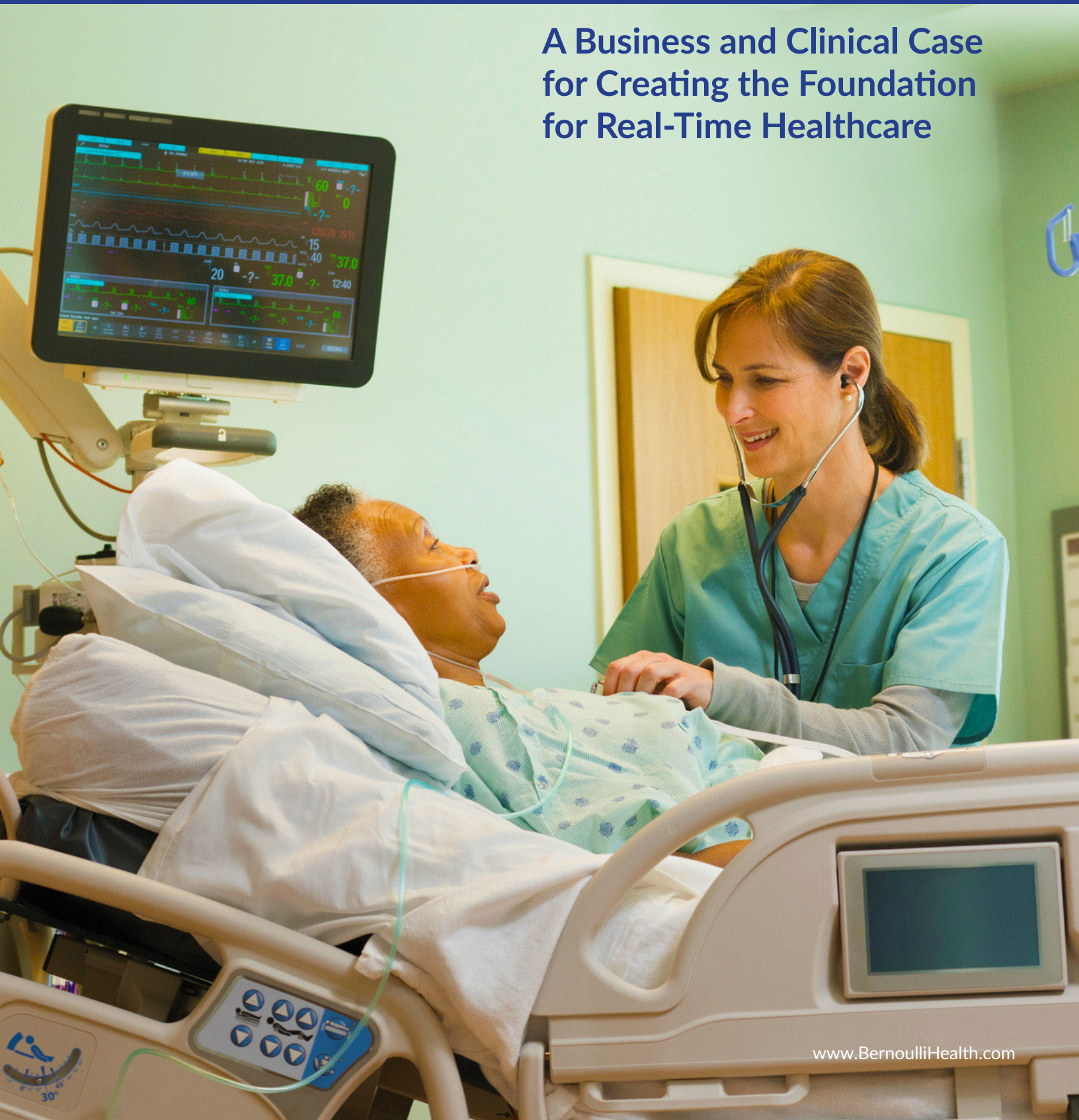
Continuous Clinical Surveillance

A Business and Clinical Case for Creating the Foundation for Real-Time Healthcare



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An Extended Hospital Stay for 'Mrs. J.'

While on vacation, an 84-year-old woman named Mrs. J. tumbles down a small set of concrete steps. The fall hurt, of course, but Mrs. J. leads an active and robust life, and she isn't going to let a bit of discomfort spoil her adventure. She pops a few Ibuprofen and carries on with the trip…

Day 1	Injury occurs
4 days post injury	Patient visits urgent care
6 days post injury	Admitted to hospital. Patient worsens unsuspectingly as vitals were not continuously surveilled.
11 days post injury	Diagnosed with multiple large pulmonary embolisms. Receives emergency anti-coagulation infusions.
14 days post injury	Discharged from hospital
18 days post injury	Completes acute rehab
3 months post injury	Finishes oral anticoagulants, radiology studies, and follow-up physicians appointments

Day 4: Four days after the fall, Mrs. J. visits her local Urgent Care Clinic. She complains of back pain, difficulty sleeping and problems rising from a prone or sitting position. She is released after being treated for abrasions, bruising and three fractured ribs and a small pleural effusion (PE). She is given instructions for pain control and pneumonia prevention.

Day 6: Mrs. J. develops extreme vomiting and diarrhea. She is taken to the Emergency Department. Further evaluation reveals two more rib fractures, acute dehydration and the still-unresolved pleural effusion. The decision to admit is made in order to observe fluid and electrolyte status, in addition to respiratory care for fractures and pain.

Mrs. J. is kept under observation on the hospital's MED-SURG unit, where the nurse-to-patient ratio is 1:4. Her recovery is slowed by persistent and extreme vomiting and diarrhea. Unable to ambulate due to pain and generalized weakness, she continues with bed rest. While compression socks were ordered, they were never used. While trying to walk to the bathroom, with assistance, Mrs. J. deteriorates into an alarmingly weakened state. She complains of chest pain and shortness of breath. Decreased O2 saturation is observed. The on-duty nurses monitor her with spot check vital signs overnight and apply supplemental oxygen. Unfortunately, periodic spot checks do not allow the nurses to fully understand what was happening with Mrs. J.

Day 11: That morning, Mrs. J.'s nurse practitioner orders a chest X-ray. Meanwhile, Mrs. J. is kept on supplemental oxygen, and it is observed by clinical staff that her mental state is waning. She is given a SQ Heparin injection in case of deep vein thrombosis (DVT). Evaluation by a pulmonary physician included a physical exam, chest CT and lower leg ultrasound. At 2 p.m. the physician diagnoses her with multiple large pulmonary embolisms that will require emergency anti-coagulation infusions - a situation that likely could have been avoided if early signs of deterioration had been detected by continuous clinical surveillance technologies.

Day 14: Mrs. J. is finally discharged from the hospital but has a long road ahead of hear. Her recovery ultimately required three additional nights in the hospital, IV heparinization and 10 days acute rehab with oral anticoagulants over the course of three months—in addition to radiology studies and physician appointments too numerous to count.

Mrs. J.'s case is typical in healthcare. Missed warning signs. Escalating complications. Increasingly costly and intensive care requirements. Patients getting sicker—even dying—right under the noses of those in their care.

Ironically, in the overwhelming majority of cases adverse events like these are avoidable.

Notably, Mrs. J.'s care team focused on acute dehydration, but overlooked that she was a status-post trauma patient. Best practice guidelines for trauma patients admitted to the hospital with fractures and bedrest is low-dose heparin to prevent DVT and PE.

During the course of her treatment, the care team neglected to observe that the primary diagnosis was trauma and not a stomach bug. Her vital signs were not under continuous clinical surveillance. If they had been, the clinical team would have caught what spot check monitoring missed—an acute change in her resting heart rate and pulse oximetry.

The inability to anticipate the early signs of serious hospital-acquired conditions, thereby requiring the need for life-saving medical intervention—as in the case of Mrs. J.—is the significant business and clinical challenge facing healthcare in the 21st century.

For the past several years, major healthcare agencies and advocates have laid the groundwork for broader utilization of continuous clinical surveillance to identify emerging threats to the health of patients, particularly as it related to the administration of opioids:

- **The Joint Commission (TJC):** In its August 2012 Sentinel Event Alert, TJC recommended that hospitals "create and implement policies and procedures for the ongoing clinical monitoring of patients receiving opioid therapy."[1] TJC updated this guidance in July 2017, recommending that hospitals "monitor the use of opioids to determine if they are being used safely," and included the tracking of adverse events, such as opioid-induced respiratory depression (OIRD).[2]

- **Centers for Medicare and Medicaid Services (CMS)**: In March 2014, CMS issued a proposed quality measure that recommended that hospitals "at a minimum have adequate provisions… for post-operative monitoring of patients receiving IV opioid medications, regardless of where they are in the hospital."[3] This came on the heels of a 2013 quality measure (#3040) recommending that "monitoring needs to be 'documented' and the time between documentation must 'not exceed 2.5 hours.'" (The 2013 guidance was criticized as insufficient for adequately protecting patients from adverse events.[4])

- **Anesthesia Patient Safety Foundation (APSF)**: APSF also endorses continuous clinical surveillance. According to association President Robert Stoelting, MD, the "APSF recommends that monitoring be continuous and not intermittent, and that continuous electronic monitoring with both pulse oximetry for oxygenation and capnography for the adequacy of ventilation be considered for all patients."[5]

A market review by Malkary suggests that "nurses who are responsible for high acuity hospital patients believe that existing clinical processes and tools are inadequate to continuously monitor patients at-risk of deteriorating conditions."[6]

Continuous clinical surveillance is emerging as the most accurate predictor of clinical deterioration. More than a patient safety measure, continuous clinical surveillance is a viable and sustainable solution for the negative costs associated with patient deterioration[7], including:

- Resource utilization
- Emergency transfers to intensive care units (ICUs)
- Length of stay
- Hospital readmissions

Though continuous clinical surveillance is regularly deployed in ICUs, there is a powerful case to be made that this capability should be scaled to other departments, such as MED-SURG, critical care, step-down and telemetry. Case in point, Mrs. J.—admitted to the MED-SURG unit—was not continuously surveilled which led to a state of undetected deterioration.

Moreover, this can be accomplished largely with modest net-new technology investments; hospitals with critical care units or ICUs already have continuous surveillance infrastructure in place.[8] Optimizing that infrastructure's capabilities and incorporating it into existing clinical workflows is the real heavy lift. However, safely surveilling high-risk populations across the enterprise and decreasing utilization of more expensive beds could provide significant cost savings for the institution and a more accurate and timely channel for clinical decision support regarding imminent, tractable problems.

> Detecting the deteriorating patient on the hospital ward is a major goal. The causes are varied, and range from underestimation of the admission diagnosis to the development of new and unrelated illnesses. The consequences range from altered management plans on the ward to ICU transfer and in some cases even to cardiac arrest and death. Physicians and nurses agree that early warning signs are often present, but are sometimes recognized only in retrospect.[9]

The best way to begin understanding continuous clinical surveillance is understanding how critical the need for it is. (See sidebar—By the Numbers).

Lessons from the Short Life and Preventable Death of Amanda Abbiehl

In July 2010, 18-year-old Amanda Abbiehl was admitted into the hospital for treatment of an infection. The virus was causing her a great deal of pain in her mouth and throat, so her physician ordered hydromorphone administered through a PCA pump. The next day, she was found unresponsive and died due to complications from OIRD.

Her parents eventually started a foundation—Promise to Amanda Foundation—"to remind patients, their families, and their healthcare providers to always monitor PCA use with oximetry and capnography."[10]

OIRD accounts for more than half of medication-related deaths in care settings.[11] However, literature reviews suggest that the overwhelming majority of cases involving respiratory compromise—97 percent—could have been prevented with the appropriate surveillance practices.[12]

> In an analysis of the Anesthesia Closed Claims Project database of patients at risk for respiratory depression over a 20-year period, Lee, et al., noted …a growing consensus that opioid-related adverse events are multifactorial and potentially preventable with improvements in assessment of sedation level, monitoring of oxygenation and ventilation, and early response and intervention, particularly within the first 24 [hours] postoperatively.[13]

Despite guidance from leading healthcare agencies and associations to adopt continuous clinical surveillance as a best practice, it remains the exception to the rule[14], particularly outside critical care settings.

Improved monitoring protocols, training programs and screening tools have likely reduced the number of cases like Amanda Abbiehl's. However, current monitoring strategies continue to remain largely inadequate for effective surveillance and timely clinical interventions.[15]

The most common practices include episodic vital signs collection, or spot vitals checks, by clinical staff and responding to alarms by physiologic devices. However, even frequent spots checks can leave patients unmonitored 96 percent of their hospital stay.[16]

Critically, spot vitals checks can result in data gaps that do not capture key vital signs activity—such as periods of apnea, low hemoglobin oxygenation levels, or periods of bradycardia or tachycardia—that take place in the span of seconds to minutes with some patients.[17]

> Jungquist, et al., note that in 42 percent of confirmed OIRD events, "the interval between the last nursing assessment and the detection of respiratory depression was less than two hours, and in 16 [percent] of the cases, it was within 15 minutes."[18]
>
> Notably, this range is far less than the spot check interval recommended by CMS' quality measure #3040 in 2013.

How Continuous Clinical Surveillance Works

There is growing evidence within the literature that continuous clinical surveillance facilitates interventions long before OIRD degrades to a life-threatening event. (See Return on Investment).

In a video produced by the APSF, the association notes that "continuous electronic monitoring of oxygenation and ventilation, when combined with traditional nursing assessment and vigilance, will greatly decrease the likelihood of unrecognized, life threatening, opioid induced respiratory impairment. The clinical significance continuous electronic monitoring offers is the opportunity for prompt and predictable improvement in patient safety."[19]

The emerging utilization of real-time data and continuous clinical surveillance offers health systems a quantitative estimate of whether a patient's condition is going to get worse over time. In contrast to electronic monitoring, which includes observation, measurement and recording of physiological parameters, continuous clinical surveillance is a systematic, goal-directed process that detects physiological changes in patients early, interprets the clinical implications of those changes and alerts clinicians so they can intervene rapidly.[20]

A continuous clinical surveillance system uses multi-variate rules to analyze a variety of data, including real-time physiological data from monitoring devices, ADT data and retrospective EHR data. The use of continuous clinical surveillance to facilitate advanced analytics—thereby detecting patterns not readily visible through intermittent spot checks—offers clinicians a quantitative estimate of whether a patient's condition is going to get worse over time.

Continuous clinical surveillance solutions that analyze real-time patient data can identify clinically relevant time-based (or temporal) trends, sustained conditions, reoccurrences and combinatorial indications that establish the trajectory of the patient state towards an adverse event prior to the violation of the limit threshold of any individual parameter. When combined with data and observations from the clinical record, a compelling story of the trajectory of a patient's condition can be obtained that forms the basis for earlier opportunities for intervention before acute onset of events require emergency measures.

Data collection and analysis are further enhanced when including methods for disseminating, analyzing and distributing these data. These features facilitate better patient care management and clinical workflow by allowing patients to be monitored remotely.

As previously stated, hospitals with continuous clinical surveillance in their ICUs can build upon existing infrastructure. In addition, hospitals can leverage their electronic health record (EHR)—as well as existing monitors, vents and physiologic devices—as a starting point for continuous clinical surveillance.

The combination of high-fidelity data with multivariate, EHR information provides a holistic and complete source of objective information on a patient that can be used for prediction and clinical decision making prospectively. As healthcare systems complete the process of implementing EHR systems involving integrated data from medical devices, the next step in the process is using these data to bring about added clinical value. All sources of data, from episodic to real-time, provide a rich source for clinical decision making and are fast becoming the future tools of the clinician and the informaticist.

Clinical Workflow—Alarm Management and Technology Infrastructure

One aspect of integration that is often overlooked is the value of clinical workflow, which can vary among hospitals and individual units. Many health system leaders and their clinical teams remain concerned about the wholesale adoption of net-new technology that may only serve to further disrupt the already intensive workflow of clinical team members.

Workflow should not be minimized because it will largely define how data are collected, displayed, and how alarm signals are communicated and to whom. Hospitals should incorporate clinical workflow as quickly and as early as possible in the process.

Alarm Fatigue

One of the major challenges in alarm management is separating clinically relevant alarms from non-actionable alarms (i.e., a sensor on a patient detached momentarily or brief self-correcting physiological responses). However, with the enormous number of alarm-enabled medical devices on the market today, default narrow alarm limits, and inaccurate default settings, can make alarm management a complex endeavor. Indeed, more than 19 in 20 hospitals surveyed express concern over alarm fatigue, and almost 9 in 10 hospitals surveyed would increase use of pulse oximetry and capnography if false alarms could be reduced.[21]

Zaleski and Venella note that a "major barrier to continuous clinical surveillance is the disruption to direct care clinical staff workflow. The risk of alarm proliferation and fatigue increases when implementing a new or additional device technology with alarm capabilities."[22]

Clinical staff and telemetry technicians can quickly become overwhelmed by the hundreds of alarm signals (up to 85 percent to 99 percent of which require no intervention) that could potentially be generated by a single patient.[23]

In Supe et al., the authors leveraged sustained alarms as the filter for notifications of clinically-actionable events. This reduced alerts from 22,812 to 13,272, which was still high enough to risk alarm fatigue. Passing multiple data time series through a multi-variate rules engine that monitored the values of HR, RR, SPO2 and ETCO2 reduced the number alerts sent to the nurse-call phone system to 209—a 99 percent reduction. In addition, that it was independently verified that no actual clinical events were missed and several patients received Naloxone to counteract OIRD.[24]

The use of smart alarms provides the flexibility to attenuate alarm signals in a way that achieves a balance between communicating contextual patient-safety specific information and minimizing spurious and non-emergent events that are not indicative of a threat to patient safety. Additionally, smart alarm strategies allow for not just the analysis of the alarm signals themselves, but also of the high-fidelity physiological data associated with them, including time trends, cross-parameter correlation, in-depth alarm sensitivity and statistical and predictive analysis.[25]

Proven Clinical Results from Peer-Reviewed Study of Real-Time Analytics (Multi-Variable Alarms)

Utilizing Standard Device Alarm Thresholds	Applying Traditional Alarm Management Techniques	Applying Bernoulli RDSS Analytics
Total issued device alarms (carnographs and pulse oximeters, excluding technical alarms)	Total issued alerts using **30-second** sustained alarm criteria	Total issued alerts using **Bernoulli's RDSS Analytics** Note: Alerted for all actual respiratory depression episodes
22,812	**13,272**	**209**
	42% Reduction	**99%** Reduction

Technology Infrastructure

For hospitals and health systems, especially those that are breaking ground on a net-new technology integration, the first step is an assessment of need. Moorman has indicated that hospitals with ICUs likely already possess much of the infrastructure to deploy continuous clinical surveillance.[26]

One of the goals of the advanced analytics that come with continuous clinical surveillance is to connect the dots from among seemingly unrelated, individual data sources. This ability enables clinicians to observe a potentially adverse course in the patient's condition over time, prior to the violation of the limit threshold of any individual parameter, and respond before costly interventions are required.

Continuous monitoring from multiple data sources—EKGs, vital signs, laboratory tests—will yield better predictive models than data from a single source. However, one of the risks of swimming in that proverbial ocean of data is that it's easy to drown. One of the objectives of analytics is to seek interrelationships among seemingly unrelated measurements and sources of data to determine whether these interrelationships can yield the detection of the onset of an adverse event that would not normally be visible by observing a single parameter or multiple parameters individually.

With the adoption of EHR systems over the past 10 to 15 years, the problem of data capture and access to data has diminished. The ability to identify events and establish better patient safety standards for patients is the new frontier.

Unfortunately, the EHR is not a convenient repository for real-time continuous data. The EHR does not capture all necessary information that pertains to short-term patient state changes that, when taken together with other information contained within the EHR, can herald the onset of adverse events. When data are not captured and reviewed in real-time, the potential exists for time gaps which can result in the failure to detect significant events that would not normally be visible at data collection frequencies of, say, once an hour or once every several hours.

However, EHRs form the foundation of how most hospitals are approaching surveillance—and make for a natural starting point.

For example, EHRs store data on patients that are relatively static—history, observations and treatment—rather than moment-to-moment changes, such as heart rate or respiration events. These changes can be quite clinically-significant, but frequently fall outside of the observation window of EHR-captured data.

There is value to augmenting surveillance strategies by adding real-time data captured from patient-connected devices. According to Malkary, "hospitals recognize the importance of real-time capabilities to enhance patient safety and improve care quality. Real-time clinical surveillance and analytics solutions can collect and aggregate retrospective data from the EHR, including patient demographics and lab values and correlate it with real-time streaming data, including temperature, heart rate, oxygenation levels, and blood pressure."[27]

For example, real-time clinical surveillance and analytics solutions can collect and aggregate retrospective data from the EHR, including patient demographics and lab values, and correlate it with real-time streaming data, including temperature, heart rate, oxygenation levels and blood pressure.

Additionally, analytics based on multiple sources of data also can help offset the problem of alarm fatigue by filtering out false or artifact signals that typically invade the high-fidelity data at the core of continuous surveillance.

Returns on Investment

Despite increasing investments by health systems, continuous surveillance remains a relatively rare capability outside of ICUs. There are several reasons for this, including a perceived lack of return of investment (ROI). Continuous surveillance remains an early and still-evolving market, but the literature supporting its application beyond high-acuity settings continues to grow.[28] This section will explore the impacts continuous clinical surveillance can have on a health system, including early identification and intervention, patient outcomes and length of stay.

Early Intervention & Rescue

A study by Supe et al., set out to determine if selectively delayed notifications using adjustable, multi-variable thresholds could identify clinically-actionable events without risking patient safety.[29] The study measured pulse (HR), oxygen saturation (SpO2), respiratory rate (RR), and end-tidal carbon dioxide (ETCO2) continuously. It then compared alarms received through the bedside monitoring devices with remote alerts annunciated through middleware, designed to trigger only after a selective delay.

An important observation made during this study was that remote alarm communication was an important aide to in-room monitoring alarm annunciation. A key argument that made for in-room annunciation in the case of conscious or waking sleep apnea patients is the room audible alert.

Yet, in every observed case of OIRD, the in-room audible annunciation had no effect on waking or stirring the patients. Hence, remote monitoring capability to catch such instances is necessary to ensure patients do not slip through the cracks.

> In a 21-month study on the impact of pulse oximetry surveillance on rescue events and ICU transfers, Taenzer et al., observed that continuous surveillance techniques decreased rescue events from 3.4 to 1.2 per 1,000 patient discharges and ICU transfers from 5.6 to 2.9 per 1,000 patient days.[30]

In a study to determine the efficacy of continuous capnography monitoring on emergency rescues, Stites et al., observed that "the pre-intervention incidence of OIRD in the setting of rapid response was 0.04% of patients receiving opioids. After the implementation of capnography, the incidence of OIRD in the setting of rapid response was reduced to 0.02%, which was statistically significant."[31]

> In addition, the authors found that continuous surveillance also reduced transfers to higher levels of care was reduced by 79% (baseline, 7.6 transfers/month; post-intervention, 1.6 transfers/month).

Length of Stay

There are a number of studies that point to continuous clinical surveillance resulting in a statistically significant impact on a patient's length of stay (LOS) in a hospital.

During an 18-month clinical trial in a 33-bed inpatient MED-SURG unit, Brown et al., observed that "continuous monitoring on a [MED-SURG] unit was associated with a significant decrease in total length of stay in the hospital and in intensive care unit days for transferred patients, as well as lower code blue rates."[32]

> The authors reviewed 7,643 patient charts: 2,314 that were continuously monitored in the intervention arm and 5,329 in the control arms. Comparing the average length of stay of patients hospitalized in the intervention unit following the implementation of the monitors to that before the implementation and to that in the control unit, we observed a significant decrease (from 4.0 to 3.6 and 3.6 days, respectively). Total intensive care unit days were significantly lower in the intervention unit post-implementation (63.5 vs 120.1 and 85.36 days/1,000 patients, respectively). The rate of transfer to the intensive care unit did not change, comparing before and after implementation and to the control unit. Rate of code blue events decreased following the intervention from 6.3 to 0.9 and 2.1, respectively, per 1,000 patients.[33]

Conclusion

Safely surveilling high-risk populations across the enterprise and decreasing utilization of more expensive beds could provide significant cost savings for the institution and a more accurate and timely channel for clinical decision support regarding imminent, tractable problems.

Hospital investments in clinical surveillance and analytics solutions are driven by organizations who are migrating toward value-based care models and are trying to achieve the objectives of value-based care, including improving care quality and outcomes, reducing clinical variation and reducing healthcare costs.[34]

Continuous clinical surveillance can be deployed to mitigate serious deterioration in patients at risk of respiratory compromise and other medical conditions in both high acuity and general care settings. Patients in intensive care units are already continuously monitored. However, many patients who experience adverse events, such as OIRD, do not follow any simple criteria for determining whether they will be at risk for obstructive or central sleep apnea. Hence, the safe alternative is to monitor everyone continuously, even on the general care floor.

By the Numbers: Justifying the Cost for Continuous Clinical Surveillance

There are a number of hospital-acquired illnesses (HAI) that could be prevented by continuous clinical surveillance. Sepsis and respiratory compromise are among the most costly in terms of resources and morbidity and mortality.

- **Industry Costs.** Respiratory failure that requires emergency mechanical ventilation occurs in 44,000 patients per year in the United States.[1A] The cost to U.S. hospitals for opioid-induced respiratory depression (OIRD) interventions are estimated at nearly $2 billion per year.[2A]
- **Hospitalization Costs**. Respiratory compromise ($22,300), ranks in the top five of 20 conditions that have the highest aggregate costs per stay due to the high frequency of hospitalization.[3A]
- **Length of Stay**. Ventilator-associated complications (VAC) can lead to longer stays in the ICU and greater rates of readmission. VAC complications add approximately $40,000 in costs to each case—or $1.2 billion in total costs annually.[4A, 5A]
- **Morbidity & Mortality**. In a 2014 study, Slight et al., found that between 2008 and 2012, 90,000 patients suffered an in-hospital cardiopulmonary arrest (IHCA).[6A] OIRD is the leading cause of in-hospital cardiopulmonary arrest (IHCA), with a rate nearly three times as high of patient who do not receive opioids or medication with sedative properties. More than 70 percent of patients who experience IHCA suffer an anoxic brain injury or die. Alarmingly, the authors noted, “More than 10,000 of these patients suffered an IHCA on the general care floor, which is where patients with relatively stable conditions are placed. We were surprised by the size of the increased odds of IHCA for a patient receiving opioids.”[7A]

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About Bernoulli

The mission of Bernoulli® Health is to improve patient safety in real time. Since 1989, Bernoulli has developed solutions including the all-inclusive Bernoulli One™ platform. A single solution for continuous patient health monitoring and clinical surveillance, medical device integration, and real-time data analytics, there are no other solutions as advanced as Bernoulli One. The Bernoulli software helps save patient lives as it continuously detects deteriorating patient conditions and notifies clinicians of potential events. This results in improved patient observation and provider workflows. Bernoulli has achieved FDA Class II clearance for use in both patient monitoring and secondary alarm management.

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