IMPROVING ONCOLOGY OUTCOMES WITH EARLIER FEVER DETECTION:

Setting a New Standard with Continuous **Temperature Monitoring**







Introduction

Vital sign checks that include the measurement of core body temperature have always played an essential role in patient health and clinical outcomes. For cancer patients whose immune systems are compromised by chemotherapy treatments, regular temperature measurement is particularly vital as a fever may be the only sign that the patient has an infection, a situation that can constitute a medical emergency. In fact, it can be life-threatening.

"Oncology is the lead application where we really see the clinical value of continuous temperature monitoring because those patients are generally immunocompromised with a high risk of infection at some point in their treatment journey," says Matt Ream, executive vice president, marketing and innovation at Blue Spark Technologies.

CONTINUOUS TEMPERATURE MONITORING: THE PROMISE OF A NEW STANDARD OF CARE

What if you could...



In this playbook, we'll take a closer look at the current standard of care for detecting fever in hospitalized patients—or episodic temperature monitoring—and compare it with continuous temperature monitoring with a wearable monitoring sensor. You will see that a faster, better, more accurate method for regular temperature monitoring offers the potential to significantly improve outcomes for patients and produce benefits for care providers and health systems. We'll present five compelling ways that continuous wearable temperature sensor technology enables an effective alternative to the current standard of care in the clinical environment.



Because chemotherapy often leads to neutropenia or a reduced white blood cell count, it can reduce a patient's ability to fight off infection. When the temperature of a patient undergoing chemotherapy or stem cell transplant is 100.4 degrees Fahrenheit (38 degrees Celsius) or higher, immediate attention is needed. At the first sign of fever, the American Society of Clinical Oncology (ASCO) recommends that the first dose of empirical initial antibacterial therapy be given within one hour. "Meeting the ASCO guideline is virtually impossible if you're taking a temperature once every four hours, and you should be administering antibiotics within one-hour."

JOHN GANNON, CEO, BLUE SPARK TECHNOLOGIES

The consequences of delay are potentially dire

Many potential adverse outcomes can result when a patient does not receive rapid, reliable temperature monitoring. These include:

- A potential increase in the risk of systemic inflammatory response syndrome (SIRS), sepsis, septic shock or death. For patients with septic shock, there is an 8% increase in mortality for every hour that antibiotic administration is delayed.¹ As many as 80% of sepsis deaths could be prevented with rapid diagnosis and treatment.²
- A longer hospital stay. A recent study demonstrated that a delay in antibiotic administration resulted in an approximate eight-hour increase in the hospital stay for cancer patients with febrile neutropenia.³
- Febrile neutropenia itself can lead to future delays in chemotherapy. This serious complication can lead to chemotherapy delays and dose reductions. It also creates significant burdens on healthcare resources used to manage these patients.⁴

Time is of the essence because the sooner neutropenic fever is detected, the sooner providers can assess the patient and begin appropriate treatments. Rapid action reduces the risk of the condition progressing to sepsis, leading to better patient care and improved overall outcomes. "Swift intervention when a neutropenic fever is detected is critical, because if it is left untreated, a bacterial infection in a neutropenic patient can lead to sepsis and death. Earlier time to antibiotics is known to correlate with better outcomes."

MUNEESH TEWARI, M.D., PH.D., PROFESSOR, UNIVERSITY OF MICHIGAN MEDICAL SCHOOL

DRAWBACKS OF THE CURRENT STANDARD OF CARE

Temperature is one of the four main vital signs for patients that must be measured accurately and monitored regularly. The current standard-ofcare (SOC) method is to measure the patient's temperature as part of the admissions procedure, as well as every four to eight hours with other vital signs unless a more frequent measurement is clinically indicated.

When it comes to affecting patient outcomes, the current standard of care, especially for cancer patients, has fallen short for numerous reasons.



One issue is the lack of consistency in the methods used for measuring temperature, which can include oral, tympanic (ear), rectal, axillary (armpit) or via the temporal artery on the forehead.

For any method, the accuracy of the reading depends on the correct placement of the thermometer at the measuring area. For example, oral thermometers must be placed in the buccal cavity of the mouth to ensure an accurate reading. And the dwell times needed to ensure accuracy differ from method to method. For oral glass thermometers, a dwell time of three to five minutes is recommended, while axillary thermometers should remain in place for seven to 10 minutes. In the ICU, pulmonary artery catheter temperature measurements, the gold standard for measuring core body temperature, require the insertion of the pulmonary artery catheter, a high-risk and highly invasive procedure prone to infection.

"There are very rare cases where continuous temperature monitoring is done now. In the ICU, temperature monitoring is typically done with a pulmonary artery catheter, which is very invasive and prone to infections," says Ream. "A comfortable wearable sensor applied to the patient is a much better way to do it."

Factors affecting accuracy

All current SOC methods require additional work on the part of the nurse taking the patient's temperature. "There are many things that need to be done to maintain the devices currently used to measure temperature in the hospital and that certainly impacts the accuracy of the temperature readings they are getting," says Ruth Phillips, vice president of medical affairs at Blue Spark Technologies. "Devices must undergo routine maintenance, calibration and cleaning to ensure accurate results."

Data entry errors

The fact that temperature data captured from each device must be manually entered in EHR increases the risk of transcription errors, delays in data entry, and other documentation errors that can create inefficiencies and adverse patient outcomes. And depending on the method used, accuracy may be impacted by factors such as mouth sores, decreased saliva, consumption of hot or cold foods or beverages prior to measurement, and operator technique.

"What we're seeing from the clinical studies we've been involved with is that temperatures aren't always taken correctly, even in the hospital by trained clinical professionals," says Ream.

THERE IS A BETTER WAY: CONTINUOUS TEMPERATURE MONITORING

With the unreliability and delays inherent in episodic temperature monitoring every four hours, the current standard of care, it's clear that a new standard of care that features regular, more accurate temperature monitoring without the need for manual intervention by a healthcare professional—or continuous temperature monitoring—is needed. Now, with the availability of continuous temperature monitoring sensors, it is possible. A wearable device that tracks patient temperatures can detect fevers and complications in hospitalized cancer patients up to four hours earlier than episodic monitoring using SOC methods. And some temperature sensors also enable patients to self-monitor through a smartphone app, providing a proven, reliable system for remote monitoring of patients for temperature increases.

IT'S TIME FOR A NEW STANDARD OF CARE

Wearable continuous temperature monitoring devices are producing significant new potential benefits for care providers and health systems—including earlier fever detection, improved patient care, infection control and shorter hospital stays.

Below, we explore five compelling reasons why it's time to replace the current standard of care with these new devices.





REASON #1: Earlier detection for neutropenic patients

Continuous temperature monitoring with wireless, wearable sensors enables faster fever detection than standard manual readings every four hours. Multiple clinical studies have confirmed the superior performance and precision of this method over traditional manual episodic monitoring methods.

A team of researchers at the University of Michigan led a study of 62 patients receiving hematopoietic stem cell therapy (HCT) or chimeric antigen receptor T cell (CAR-T) immunotherapy who were monitored by manual temperature measurement every four to eight hours and continuous monitoring of temperature every two minutes.

"We found that the CTM [continuous temperature monitoring] approach provides several hours of lead time for early detection of febrile adverse events," says Dr. Tewari, a member of the University of Michigan research team. "When we looked at lead time for infection and CRS [cytokine release syndrome] detection separately, we found that the lead time was even higher for infection, with CTM detecting fever associated with infection often more than 12 hours before standard of care."

In other studies, a wearable continuous temperature monitoring device also detected fevers earlier than the standard of care, even fevers that were missed entirely by the standard of care, a situation that effectively delayed treatment of those patients and created the potential for adverse outcomes.

MICHIGAN MEDICINE

Study subjectsPatients receiving HCT or CAR-T cell therapyResults• 89% of fevers detected earlier than the SOC

- Fevers caused by infections detected an average of 18.5 hours earlier
- Fevers caused by CAR-T CRS detected an average of 4.4 hours earlier



Study subjects	Adult bone marrow transplant and high-dose chemotherapy patients	
Results	• Fever detection an average of 2.4 hours earlier than SOC	
	• Detection of first onset of neutropenic fevers an average of 11.4 hours earlier	



Study subjects	Pediatric patients undergoing hematopoietic stem cell transplant
Results	 Fever detection for 2 patients more than 12 hours earlier than SOC
	 Fever detection for 2 patients where SOC failed to detect
	• Safe and tolerable for patients

14 months-18 years of age

Greater frequency may lead to earlier fever detection

Increasing the frequency of temperature measurement increases the probability of detecting a fever sooner than the current standard of care. Compared with the current standard of measuring every four hours, the device used in the studies cited above measures and transmits the patient's current temperature every 10 seconds.

METHOD	DURATION	READINGS/DAY
CURRENT STANDARD OF CARE	EVERY 4 HOURS	6 TIMES PER DAY
CTM DEVICE	EVERY 10 SECONDS	8,600 TIMES PER DAY

Compared with measurements taken every four hours (or six times per day), the continuous temperature monitoring device takes an estimated 8,600 temperature readings for each patient every day—significantly increasing the likelihood of detecting fever much earlier.

The ability to detect fevers sooner benefits everyone:

- Patients can be treated earlier, reducing the risk of sepsis, the number-one cause of death and costs in hospitals
- Patients can often be discharged sooner, reducing the risk of nosocomial or other infections
- Patients can often receive remote treatment instead of readmission
- Manual measurements by caregivers is reduced, enabling them to focus on more critical tasks
- Hospitals can realize significant savings from reduction of readmissions

REASON #2: EASY INTEGRATION INTO CLINICAL WORKFLOWS

Many of the sensors embedded in the continuous temperature monitoring devices can automatically capture and enter temperature data into EHR and provide a deeper dataset than the existing standard of care. They can also be seamlessly integrated into existing clinical workflows.

Nurses appreciate the convenience of these devices because the automatic temperature readings eliminate the need to wake the patient to take a reading. This also saves the provider and the hospital system considerable time and costs. And many wearable temperature monitors send data wirelessly to EHR for safe and secure storage of patient data.

"We commissioned a study of a 100-bed hospital to determine the time savings efficiency that could be realized by replacing a manual temperature reading with a continuous monitoring sensor," says Gannon. "Based on an average of five minutes to take and record each temperature, the sensor method would reduce the amount of hands-on time to take and record the temperature by 57,000 hours per year."

REASON #3: EARLIER HOSPITAL DISCHARGE

CAR-T and bone marrow transplant cases typically involve a 30-day inpatient program. "The reality is that, for approximately the last seven to 10 days of that inpatient period, patients are kept in the hospital to monitor for fever," says Ream.

Using a continuous temperature monitoring device would enable patients to be discharged much earlier, resulting in a more comfortable experience for patients and significant cost savings for the hospital. "While continuous temperature monitoring benefits clinical staff and patients, the financial benefits for the hospital can also be significant," says Ream. "As the average cost of an oncology bed is approximately \$8,000 per day, early discharge for a patient represents significant cost savings for the hospital."



Discharged cancer patients need to take their temperature at regular intervals throughout the day. Yet, self-reported fever is often much less reliable in the outpatient setting, and the frequency of temperature measurements is lower, causing delays in fever detection.

Devices with continuous temperature monitoring sensors provide a proven, reliable system for remotely monitoring patients for temperature in real time. Because patients find a noninvasive wearable temperature monitor to be comfortable and easy to work with, they are more likely to wear them consistently. And, because they alert when fever develops without requiring any action on the patient's part, patient compliance is a non-issue.

With the ability to receive early alerts at the first sign of a fever, patients can take steps to receive the necessary treatment sooner than ever. "In the case of a fever related to CRS, which can progress to a potentially deadly stage, lead time may be especially helpful for CAR-T cell administration in the outpatient setting. An earlier alert offers enough time for patients to return to the hospital for early treatment of CRS before it progresses to a more severe grade," says Dr. Tewari.

REASON #5: GOLD STANDARD-COMPARABLE RESULTS

The pulmonary artery catheter (PAC), the current gold standard for core temperature measurement, requires insertion of the PAC, a procedure that is high-risk, invasive and prone to infections.

A recent Cleveland Clinic study demonstrated that a wearable device for continuous temperature monitoring achieves results comparable to the PAC gold standard: Paired temperature measurements for the PAC and [a continuous] temperature monitoring system were taken simultaneously every two hours for an eight-hour period on 60 patients in two Intensive Care Units (ICU). In analysis, [the CTM] measurements were in agreement with PAC temperature measurements (± 0.3 ° Celsius) and the precision of the two methods were not significantly different.⁵

The superior fever detection provided by a wearable continuous temperature monitoring device clearly facilitates outpatient and all non-ICU-based care, reducing the burden on the ICU and patient expenses.

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DETECT FEVERS EARLIER WITH A BETTER STANDARD OF CARE

Febrile neutropenia is a medical emergency in cases that involve patients undergoing chemotherapy. Antibiotic therapy must begin within the first hour of clinical signs of infection—a temperature greater than or equal to 100.4 degrees Fahrenheit (38 degrees Celsius). The current standard approach to monitoring temperature in hospitalized patients every four to eight hours runs the risk of delays in the diagnosis of febrile adverse advents.

"I would predict that if continuous temperature monitoring becomes the standard of care in both the inpatient and outpatient settings, by enabling earlier administration of antibiotics, it would have a major positive impact by reducing sepsis, ICU admissions and deaths due to infection," says Dr. Tewari.

Noninvasive, wireless, wearable sensors take the standard of care for regular temperature monitoring to a new level by providing readings with greater frequency, raising the possibility of earlier detection and diagnosis of fever and associated adverse events. Multiple studies have demonstrated the ability to detect a rise in body temperature significantly earlier in a majority of patient cases.

Wearable devices embedded with temperature monitoring sensors like TempTraq[®] from Blue Spark Technologies offer a promising new alternative to the current standard of care. The TempTraq wearable patch monitors the patient's temperature in real-time and wirelessly uploads the temperature data to the Blue Spark Technologies HIPAA-compliant cloud server. Data from the secure server can be integrated with EHR, central clinical workstations, patient bedside monitors and mobile devices to provide clinicians with temperature data visualization and data mapping to the desired patient record fields.



CLINICIAN DASHBOARD

From an infrastructure perspective, implementing the TempTraq system is a simple, low-touch process. It can be integrated directly into a hospital's central monitoring system and EHR for safe and secure storage of patient data. And because the dashboard is a web browser, access by clinicians is easy and intuitive. In fact, a healthcare facility can have the TempTraq system up and running for the clinical staff in a matter of days. The system is scalable and can support a single hospital or a multi-hospital/physician group healthcare system.

TempTraq offers the potential to improve clinical outcomes significantly for patients. FDA-cleared and HIPAA compliant, with wireless, Bluetooth capability, TempTraq now provides clinicians with a continuous, smarter way to track, log, and respond to fevers faster than ever before.

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Founded in 2003 in Westlake, Ohio, Blue Spark Technologies is dedicated to pioneering continuous vital sign monitoring solutions that improve patient care, reduce readmissions, and optimize hospital reimbursement. Its medical devices contain no hazardous substances, making them safe, disposable, and eco-friendly. Blue Spark's flagship product, TempTraq[®], is the only continuous, disposable adhesive patch for real-time body temperature monitoring for up to 72 hours. The comfortable, wireless TempTrag sensor transmits data via Bluetooth®. As an FDA Cleared Class-II, EU-Cleared Class II, and HIPAA-compliant medical device, it can upload real-time data to the TempTrag Connect platform, which integrates seamlessly into a hospital's central monitoring station or can be accessed in outpatient settings via Apple[®] or Android[™] compatible mobile devices. Through continuous monitoring, TempTrag improves the way healthcare professionals monitor for fever, providing a simple, effective way to elevate the standard of care delivered in the clinical environment. For more information about TempTrag®, visit https://temptraq.healthcare.

LEARN MORE

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