What's the Big Deal About FDA Clearance? Plenty! The benefits will rock your world!

We all know the importance of having vitals measurements automatically downloaded to our EMR system. The simple benefits: time savings and error elimination. But we all want more—we want outcome improvements! That's why we need a vitals integration solution that delivers the advantages of FDA Clearance.

How do devices transmit to my EMR? Integrated systems transmit data to and from your EMR in many different physical forms. Some integrations run on the medical device itself, some on an attached computer or tablet—but each has its own features and advantages. For example, vital signs carts with an attached tablet may offer mobile kiosks features that allow the user to access additional applications like the ones used to document ADLs or nursing assessments. This design helps minimize the need to acquire additional wall kiosks or work stations. What lies beneath the surface is the software that makes those connections. The software determines how efficient and effective the system is, whether new devices or measurement types can be added, and most importantly, what the system can analyze and provide as meaningful feedback to the user from the collected data flowing back and forth.

What's the difference between FDA Cleared and the more restricted MDDS classification? The fundamental difference between the MDDS (Medical Device Data System) and Integrated Clinical Software with FDA Clearance boils down to what they can do with the data. MDDS are not required to get pre-market clearance from the FDA, so their software is narrower in scope to avoid the complicated scrutinizing and precision-oriented process of FDA clearance, inspections, and audits. The trade-off is that MDDS software is limited in its functionality to transferring, displaying, and converting the data into standard formats like HL:7 for simple, basic integration. On the other hand, an FDA cleared system is able to not only engage in the data transfer, but may also utilize analytics, data interpretation, alerts, thresholds, and other clinically relevant feedback from the data and is able to engage in true, comprehensive "patient monitoring."

What does this mean to you as a clinician? Tiffany Hafner, Director of Nursing at the Lodge Health and Rehabilitation Center is one of the many clinical leaders feeling the increased scrutiny by CMS and referral partners on preventable hospital readmissions in Long Term Care. Her organization, Greystone Health Network, has implemented Constant Care Technology's CareConnection FDA cleared Integrated Clinical Software and is reaping the benefits from both the clinical tools and the direct integration with her EMR, PointClickCare.

> *"Now that the vitals arrive in PointClickCare within minutes, our nursing team has the option to use those most recent vitals to administer meds. In addition, we're finding that our ability to intervene and prevent a hospital readmission has vastly improved. We are all so much more confident of the measurement and documentation accuracy. I'm no longer seeing a temperature entered at 986°F because someone missed a decimal while entering data. We are human—we make mistakes, but when a resident's health is at stake, we need this kind of technology to ensure the best care."*

If your facility shares Greystone's concerns, then you'll want to embed the benefits of connecting your medical devices through an Integrated Clinical Software with FDA clearance rather than a system that only holds MDDS certification and is limited to the most basic and confining data transfer. Integrated Clinical Software delivers not only data transfer (like an MDDS) but also offers more advanced features like predictive analytics for early warnings on patient's conditions, alerting when patient readings are out of range or trending negatively, and allowing facilities to set measurement thresholds and trending preferences for their patients in the system. An example of leveraging the value of information from an FDA cleared integration is CareConnection's SMART*Reports used by Directors of Nursing and Nurse Practitioners to identify at risk residents and trigger proactive intervention.

What's important to me about SMART*Reports? CareConnection's algorithms analyze and report on the subtle combinations of changes in condition and trends in the vital signs sent through the Integrated Clinical System. A group of Nurse Practitioners who used the SMART*Reports gave several examples of instances in which SMART* analytics identified and notified the care team of subtle, but important clinical downturns in condition in otherwise asymptomatic patients:

> *"This didn't prevent a hospitalization, it actually led to one, but **likely saved the patient's life.** I had a patient two weeks ago with sudden onset Hypoxia identified on SMART*. The patient displayed no shortness of breath and lungs were clear. She is morbidly obese and status post new knee replacement. Chest x-ray was performed stat and results were negative. She had no history of Pneumonia or COPD, therefore leading me to concern for Pulmonary Embolism. She was sent to hospital for PE protocol and she had two P.E.s and a DVT."*

> *"I have had several notifications that have caused concern triggering me to check on patients. I have had 2-3 patients with vital sign changes that alerted me they were becoming septic when, in fact, no other signs or symptoms were apparent or reported. Labs were obtained and showed elevated WBC counts, positive urinalysis for one patient, and pneumonia in another. I use the SMART*Reports frequently to track Blood Pressures, especially when changing medication dosages or adding a new agent. I had another patient who showed up on my report, and was alerted to run labs to check her hemoglobin & hematocrit which had fallen to transfusable levels. Many of our patients are unable to complain when feeling sick, so this system allows us to utilize a consistent monitoring tool to alert us when something is wrong, often before any of the clinicians can see signs of deterioration."*

What's the bottom line? When you choose your vitals integration system, be it an MDDS or Integrated Clinical Software, always consider the full scope of benefits you expect to obtain from the technology for your facility and perform due diligence. Reputable companies should not have an issue providing you with documents to support their regulatory compliance claims, their data analyzing capabilities, or samples of their reports. Be sure to select a HIPAA-compliant system, and request a copy of the security audit summary to ensure the company is capable of protecting your patient data. If a company is selling an FDA cleared product, you'll want to request their 510K number or their 510K clearance form. Be wary of companies or products without FDA clearance that may be promising features that do not fall into the MDDS classification.

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