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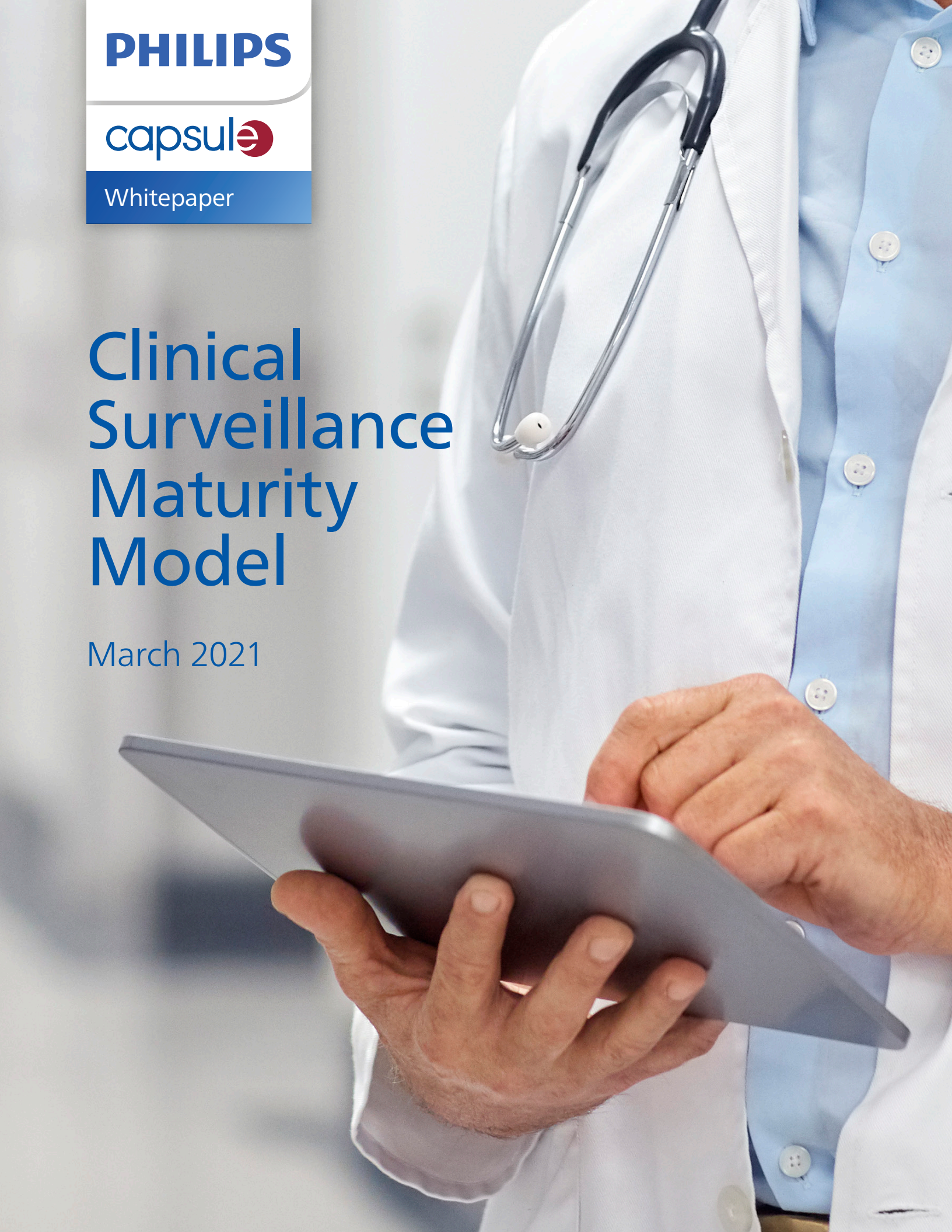
Whitepaper

Clinical Surveillance Maturity Model

March 2021

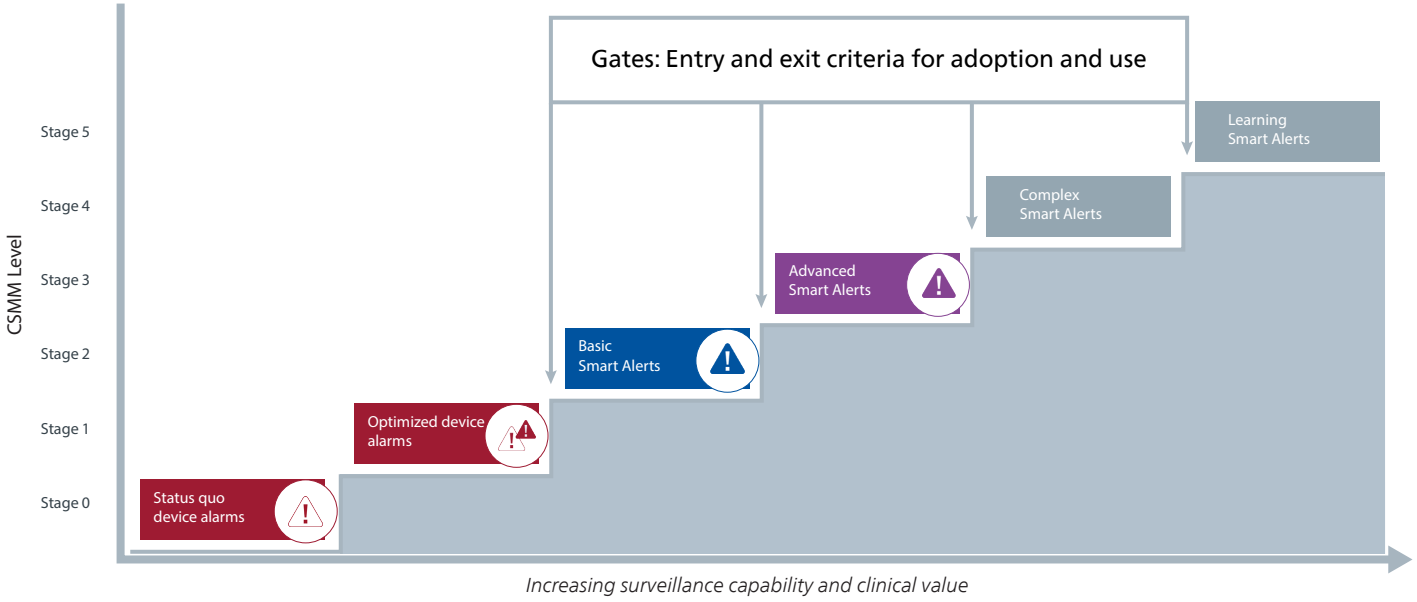


Background

The Clinical Surveillance Maturity Model (CSMM) was developed to relate stages of operational clinical surveillance maturity conceived as a methodology to reduce nuisance and non-clinically actionable medical device alarms and to speed the earlier identification of emergent, clinically-actionable patient conditions and events. The CSMM is based upon other types of maturity models that have been developed over the course of the past three decades. These include the Systems Engineering Capability Maturity Model (SE-CMM) developed by the Software Engineering Institute of Carnegie Mellon University[1], the Software Capability Maturity Model (SW-CMM)[2], and the Adoption Model for Analytics Maturity (AMAM) "measuring the capabilities [an] organization has gained from technology and surrounding processes".[3] These established models informed the creation of the CSMM because they provide a staged, gated approach to evolving levels of organizational readiness which are more easily measured along a continuum from an initial point to a fully functioning implementation of clinical surveillance.

A depiction of the CSMM is shown in Figure 1. The model focuses on the evolution of clinical surveillance from a current state of status quo medical device alarms to a more advanced form of clinical notification, or smart alert, that is the heart of clinical surveillance. Smart alerts are notifications that incorporate more contextual information surrounding the patient, such as demographics, metabolic panels, and other information. It is envisioned that, long term, smart rules can evolve to make use of artificial intelligence and machine learning.

Figure 1: Clinical Surveillance Maturity Model levels



Model Structure

Figure 2 (below) contains both the stages of evolution associated with the maturity model and curves that depict the concomitant decline in nuisance alarms and the simultaneous increase in clinical benefit associated with the use of smart alerts. These curves illustrate the effect of deploying and using more smart alerts over time: reduce non-clinically actionable nuisance alarms that impact patient safety and are cause for distraction to the frontline provider while at the same time improve the clinical specificity of the annunciated alerts. *In summary, the objective is to reduce non-clinically actionable notifications and increase the likelihood that those notifications that are issued are of greater clinical benefit.* The curve trajectories of decreasing non-clinically actionable notifications are generalized based on nuisance alarm reduction approaches and increases in specificity identified in the literature over more than a decade of applied clinical research.[4,5,6,7,8]

Figure 2: Clinical Surveillance Maturity Model stages, gates and clinical impact

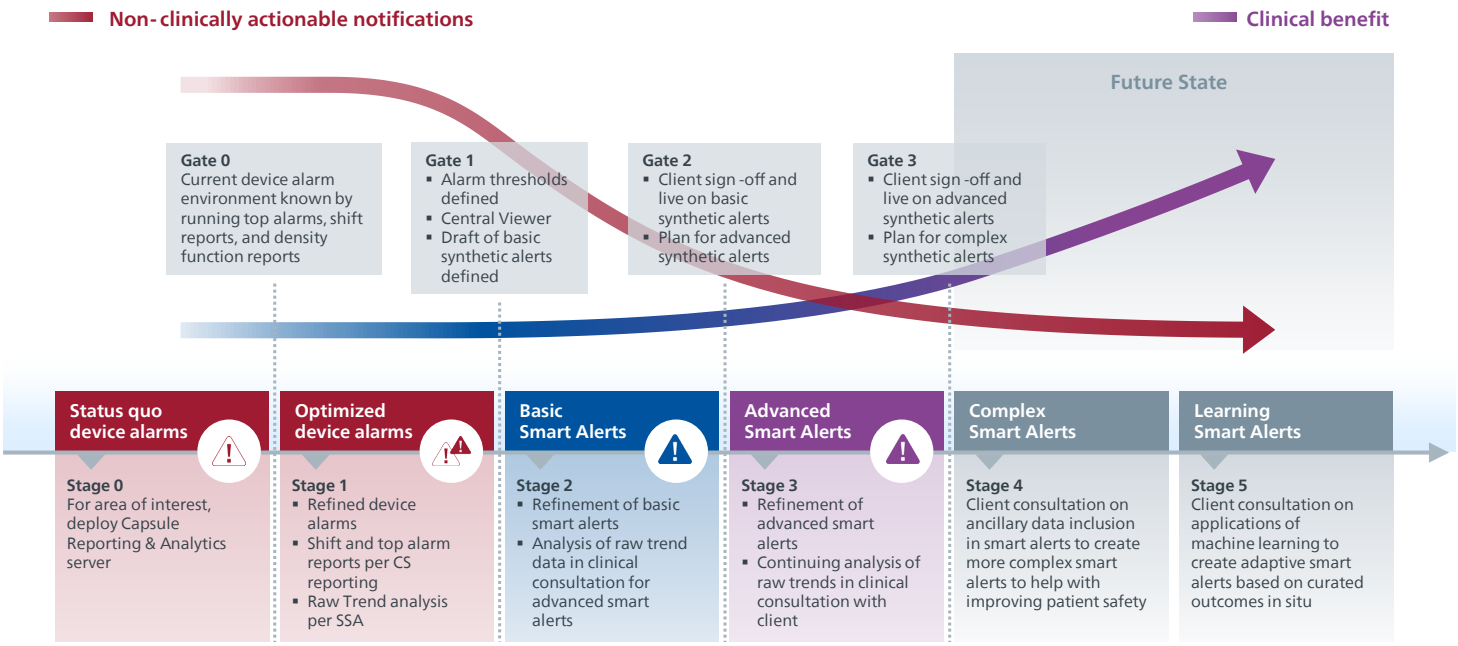


Table 1: Six stages of the Clinical Surveillance Maturity Model

Stage 0: Status quo device alarms

Client Implication: The healthcare system's current state of medical device alarms. This is the state of medical device alarms as they exist at the time of initial client contact. This stage may include healthcare system policies and recommendations from the medical device vendors, alarm committees, and best practice guidelines.

Notes: In this stage, the healthcare system may have configured medical device alarms based upon vendors' recommendations or departmental requirements, patient demographics, alarm committee recommendations or edicts, healthcare system policies, clinical guidelines, or any combination of these. The selection of medical device alarm thresholds may be optimized per patient. Yet, the healthcare system may not be aware of the ramifications of medical device alarm thresholds and their implication on alarm fatigue, nuisance alarms, or clinical benefit or specificity in identifying patient conditions as being clinically actionable.

The client may be using transmission of medical device alarms to remote central stations. Data collected from patient medical devices may or may not be integrated into the electronic health record. In this stage of clinical surveillance deployment, the process of education is key and, communication with frontline clinical stakeholders is essential to establish expectations and clear impediments to full clinical surveillance deployment. During this stage Capsule Reporting and Analytics is essential to quantify the state of current alarms and report back to the clinical and non-clinical stakeholders what their current alarm annunciation load is by department, alarm type, shift, etc.

Stage 1: Optimized device alarms

Client Implication: Medical device alarms that are not specifically tailored or are simply defaulted based upon vendor guidelines can result in enormous quantities of nuisance alarms. This assertion has been well documented in the published literature.[9,10,11,12]

Notes: In this stage, the objectives are: (i) to optimize the existing medical device alarms that are annunciated throughout the healthcare system; (ii) to validate that best practice policies are accommodated in the assessment of the current medical device alarms; (iii) to ensure that the baseline nuisance alarms are vetted by stakeholders within the healthcare system; and (iv) to validate whether staff are educated as to the implications medical device settings and policies can have on nuisance alarms. This stage establishes the trajectory for smart alerts because it ensures that the best possible medical device alarm laydown is established. Capsule Reporting and Analytics seeks to quantify and provide evidence of the alarm optimization via obtaining alarm signal and raw data measurements. Through this process of investigation, parameter interrelationships, sensitivities, correlations, and insights are obtained that assist in providing an "early indication" as to the potential benefit of introducing smart alerts into the environment.

Stage 2: Basic Smart Alert

Client Implication: The analysis of measured parameters and medical device alarms performed in Stage 1 can reveal correlations and trends that establish more specific types of alerts using techniques such as combining measurements or identifying repeated signal measurement behavior that carry physiological significance and serve as a proxy for more clinically beneficial notifications over medical device-initiated alarm signals. These measured parameter behaviors are instantiated in the form of sustained, consecutive, and combination alerts that fall into the realm of what is defined here as a Basic Smart Alert. That is, the use of patient measurements obtained from the various medical devices either alone or in concert with one another provide for new types of notifications that, through their combined or unique behavior, identify more clinically beneficial notifications than the standalone medical device alarms can. This is particularly true of combining measurements of various sorts from different pieces of medical equipment associated with a given patient.[5,13,14]

Notes: The key objective in this stage is achieving operationally deployed Basic Smart Alerts. Examples of these types of Basic Smart Alerts can include ratios of parameters, such as peak-inspiratory-pressure-to-expired-tidal-volume (*PIP/Vte*), or rapid-shallow-breathing (*RR/Vte*), or consecutive occurrences of measurements breaching thresholds within a given time window. These types of combination and consecutive alerts are termed smart because they are created externally by the Clinical

Surveillance software and they are uniquely specific to the patient population, drawing upon measurements from one or more separate medical devices or other sources, such as patient demographics from admission, discharge, transfer (ADT) messaging available from the registration system.

While some medical devices do create certain types of smart alerts (e.g.: Medtronic Integrated Pulmonary Index™), these types of alerts are still a bit reactive because they are based on thresholds themselves (e.g.: rapid-shallow-breathing-index, RSBI > 105). Nevertheless, these Basic Smart Alerts will carry more specificity and clinical benefit due to their accommodating more physiologically meaningful interrelationships among the parameters comprising them. There will still be nuisance alerts associated with these Basic Smart Alerts, and the healthcare system may note that alarm quantities overall will increase initially with the addition of these Basic Smart Alerts, this is a transient experience as the clinicians need to experience and gain trust in the Basic Smart Alerts. As trust is gained, the Basic Smart Alerts will take precedence over the medical device alarms resulting in an overall reduction in noise over time.

Stage 3: Advanced Smart Alert

Client Implication: The work performed in Stage 2 establishes the necessary pathway for evolving into higher specificity of prediction for more advanced and clinically actionable alerts. These more advanced smart alerts focus on the trending or evolving behavior of measurements, such as evolving hypotension in septic patients (i.e., lowering of the blood pressure), or changing respiration and increasing carbon dioxide in post-operative patients receiving pain medication (i.e., evolving sleep apnea or respiratory depression).

Notes: A key objective in this stage is improving clinical specificity and benefit. Advanced Smart Alerts may be designed to trigger based on clinical trends that are of interest or import to the frontline clinician, which might translate into increasing clinical benefit. Advanced Smart Alerts draw upon the data obtained from the bedside medical devices, and other data already identified under Basic Smart Alerts, which are derived and made available for study through Capsule Reporting and Analytics. A greater level of consultation is required with clinical stakeholders to develop these Advanced Smart Alerts as they necessitate deeper clinical understanding.

Stage 4: Complex Smart Alert

Client Implication: The Complex Smart Alerts continue the work of the Advanced Smart Alerts but with an expanded information base, drawing upon more knowledge of the patient demographics and tertiary information, such as comprehensive metabolic panels, patient history, and even imaging data.

Notes: Because richer information is brought to bear on individual patients, the expectation is that the specificity of Complex Smart Alerts will increase, and nuisance or non-clinically actionable alerts will continue to decrease in this stage. This stage of evolution is still within the continuing domain of Clinical Surveillance product development so further elaboration is speculative at this point.

Stage 5: Learning Smart Alert

Client Implication: One can imagine alerts that can evolve and learn from greater clinical insight, more acquired information, and tailor themselves adequately to the needs of the individual patient, based on the protocols and requirements of the health system, department, or even State mandated guidelines. This is the concept and mission of the Learning Smart Alert.

Notes: The Learning Smart Alert is a vision of the future which Capsule is interested in pursuing and is part of its long-term mission related to helping to improve patient safety and the clinician-patient experience. While these types of alerts are still a vision, it is anticipated that this stage will draw upon multiple types of methods involving expert systems, machine learning and artificial intelligence.

Summary

The Clinical Surveillance Maturity Model portrays the evolution of smart rule creation and implementation as a healthcare system evolves from basic medical device alarms to more context-rich and clinically-actionable notifications. The development and adoption of smart alerts involves a highly consultative interaction among Capsule Clinical Informatics and healthcare system personnel. The adoption of the smart rules also depends upon clinical trust in the smart rules, which is obtained and accrued over time and with continuing success. For this reason, it is generally observed that clients can potentially evolve from Stage 0 through Stage 1 within several weeks and is dependent in part of client discretion. Adopting Basic Smart Alerts can take longer, but is also potentially achieved in enterprise departments within several months. Evolving Smart Alerts beyond Stage 2 is in work presently at several client sites and involves close supervision of the healthcare staff and consultative involvement from the Capsule Clinical Informatics Group.

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