# Closed-Loop Anesthesia: Ready for Prime Time?

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Everyone reading this editorial has personal experience with devices that use closed-loop control. Cruise control in our automobiles is a good example, and most of us are comfortable using it to prevent going over or under the speed limit, especially during long drives or when we are distracted. Most of us also know that modern commercial aircraft have sophisticated autopilots that maintain speed and altitude during steady-state flying. But these autopilots are also often used during landing and takeoff; they are used because they provide smoother control, increase safety, and conserve fuel compared with manual pilot control.[1]

This issue contains 2 meta-analyses of medical closed-loop controller performance.[2,3] Both conclude that compared with manual control, automated systems consistently provide better stability of parameter set points. Neither study found evidence that controllers were worse in any measure of performance.

Both meta-analyses overlapped in their investigation of sedation and anesthesia control. Although there were slight differences in the studies included in each of these analyses, together, they identified 19 discrete randomized comparisons of manual versus automated control. These original studies were undertaken at hospitals in Belgium (2 studies), Canada (2), China (2), France (6), India (6), and Switzerland (1). No studies were performed in the United States.

With such promising results, we might expect that automated control systems might be incorporated in future anesthesia devices. They may be, but will we ever see these systems used in the United States?

After all, there are many devices and pharmaceuticals that are widely used in the world but not approved for use in the United States. For instance, we still do not have target-controlled infusion pumps that are approved for use and universally utilized in every other country (ironically, a popular control algorithm, Stanpump, was developed in this country).[4]

With the following rare exceptions, to date, the US Food and Drug Administration (FDA) has not approved physiologic closed-loop control (PCLC) devices. The IVAC Titrator (IVAC Corporation, San Diego, CA), a nitroprusside controller used to regulate blood pressure after open heart surgery, was approved for use in 1987.[5] Ventilators incorporating pressure-regulated volume control mode have been approved; however, the FDA has not approved PCLC in any other anesthesia or critical care devices. For example, closed-loop control of inhaled anesthetics to achieve a set end-tidal anesthetic concentration is available on anesthesia machines in Europe, Asia, and Australia but not in the United States.[6]

This may change …

In October 2015, the FDA published a discussion paper and held a workshop that indicated its interest in defining a pathway to approve such devices.[7] At the workshop, the FDA acknowledged that although there are potential advantages to closed-loop control, it is concerned about safety and does not currently have processes to evaluate closed-loop control devices to ensure that problems have been identified and corrected before general use. The agency identified 3 main types of PCLC devices that it would consider for use in anesthesia and critical care: 1) anesthetic delivery, 2) mechanical ventilation, and 3) hemodynamic/fluid management. In addition to this list, we would add blood glucose control.

The FDA stressed during the workshop that device approval depends on demonstration of a positive benefit to risk ratio. But it acknowledged that such demonstration could be difficult and costly. As can be seen from the articles in this issue, the experience with closed-loop control in anesthesia and critical care is still quite small. Pasin et al[3] found 12 randomized comparison studies of intravenous anesthetic administration during surgery in adults, with a total of 619 patients in the automated control condition. Brogi et al[2] found 15 randomized trials comparing closed-loop control for anesthesia or sedation in a total of 484 patients in the closed-loop condition. Taking overlap into account, these 2 analyses summarize the experience in a total number of only 744 patients.

The benefits found in these 2 analyses were modest improvements in process indicators. Brogi et al[2] found that automated systems increased by 17.4% the proportion of time that a set variable (eg, Bispectral Index™ [BIS™], Covidien-Medtronic, Minneapolis, MN) was maintained within a desired range (eg, 40–60). They concluded that safety was improved because there was less overshoot and undershoot of anesthetic level, as indicated by BIS level. Pasin et al[3] found that closed-loop intravenous anesthetic delivery was associated with a 0.37 mg/kg lower per-weight dose of propofol administered for anesthesia induction and a 1.67-minute faster recovery time. They also found that BIS values were more precisely maintained, and

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that there were no differences in hemodynamics between manual and automated control groups. However, neither study found enough evidence to make statements about outcomes, such as awareness, postoperative morbidity, or mortality. Other potential benefits of closed-loop control include reduced clinician workload, consistent application of best clinical practices, and reduced accidents resulting from human slips and distractions.

However, automated systems have the potential to introduce new hazards. These can arise at different levels. Closed-loop control depends upon having a signal on which to provide feedback; problems arise when the signal is noisy, discontinuous, inaccurate, or affected by another process. For instance, a nitroprusside controller that feeds back on invasive mean arterial pressure might give too much nitroprusside if the transducer is lowered. Other processes besides level of sedation can affect BIS levels.[8] At another level, closed-loop feedback can be accomplished using a number of mathematical methods, each of which has advantages and disadvantages. Each can potentially yield erroneous output in extreme circumstances, and feedback algorithms are not standardized. Both Brogi et al[2] and Pasin et al[3] found significant heterogeneity in performance between the different studies, but the articles did not analyze whether some algorithms were better than others. Hazards at the human level are probably the most difficult to predict. Unexpected consequences such as overreliance, complacency, loss of situational awareness, and skill degradation induced by autonomy have been seen in other domains.[1] There could be another important consequence: Introducing feedback-controlled devices into the anesthesia work domain in the United States might give the impression that anesthesia provision can be automated, with the implication that anesthesiologist involvement is not necessary. This would certainly be the impression to those who think that anesthesia only consists of pushing intravenous drugs and turning the anesthesia vaporizer on and off. However, we all know that anesthesia care is much more than that, and that defining the medical strategy and goals of resuscitation from the preoperative through the postoperative period is much more critical than administering the drugs. Pilots still control every commercial aircraft, but they increasingly do this by setting and monitoring advanced autopilot technologies. Similarly, we are confident that there will be a continued need for anesthesia professionals, but they may provide care using increasingly automated medical devices. Automation will not reduce the need for anesthesiologists during surgical cases, but it will change their role.

In summary, the 2 articles in this issue show that closed-loop feedback of anesthesia delivery consistently yields more stable control with less overshoot and undershoot, faster recovery from anesthesia, and lower anesthetic doses. But further evidence of a positive benefit to risk ratio will be needed before such devices are approved for use in the United States. The FDA has an interest in working with clinicians and device manufactures to develop a process for evaluating devices that use this technology and hopefully will issue formal guidelines for all stakeholders. This will take time, and it may have significant societal effects on our specialty. But it is worth doing in our ongoing drive to increase consistency in anesthesia care delivery, and thereby patient safety.

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# Intraoperative Clinical Decision Support for Anesthesia: A Narrative Review of Available Systems

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With increasing adoption of anesthesia information management systems (AIMS), there is growing interest in utilizing AIMS data for intraoperative clinical decision support (CDS). CDS for anesthesia has the potential for improving quality of care, patient safety, billing, and compliance. Intraoperative CDS can range from passive and post hoc systems to active real-time systems that can detect ongoing clinical issues and deviations from best practice care. Real-time CDS holds the most promise because real-time alerts and guidance can drive provider behavior toward evidence-based standardized care during the ongoing case. In this review, we describe the different types of intraoperative CDS systems with specific emphasis on real-time systems. The technical considerations in developing and implementing real-time CDS are systematically covered. This includes the functional modules of a CDS system, development and execution of decision rules, and modalities to alert anesthesia providers concerning clinical issues. We also describe the regulatory aspects that affect development, implementation, and use of intraoperative CDS. Methods and measures to assess the effectiveness of intraoperative CDS are discussed. Last, we outline areas of future development of intraoperative CDS, particularly the possibility of providing predictive and prescriptive decision support. (Anesth Analg 2017;124:603–17)

A clinical decision support (CDS) system is a computer system that provides assistance to a health care provider in clinical decision making. It assimilates multiple patient data elements to generate case-specific advice. CDS systems can be either knowledge based (or expert systems based) or nonknowledge based.[1] Knowledge-based systems use expert clinical knowledge, typically implemented as conditional logic, to infer clinical events. However, non–knowledge-based systems use artificial intelligence to derive knowledge or patterns from a clinical data set. CDS systems should be differentiated from a closed-loop system. In a CDS system, the care provider uses the advice of the system to perform an intervention. However, in a closed-loop system, there is no human intervention, but rather the system automatically performs treatment actions through an actuator. An example of a closed-loop system is the artificial pancreas that uses glucose measurements and a control algorithm to automatically titrate insulin doses via a pump.[2,3]

Intraoperative CDS was first introduced in 1952 by Himmelstein and Scheiner[4] with the invention of the cardiotachoscope. For the first time, clinicians were given either a visual or an audible alarm almost immediately when a patient's heart rate was out of range. Over the past half-century, CDS capabilities have improved leveraged by technological advancements. In today's operating room, increasing adoption of anesthesia information management systems (AIMS)[5–8] has opened the doors for developing real-time CDS to provide immediate feedback and guidance to deliver safe and best practice anesthesia care.

AIMS were first developed primarily as a recording device to perform automatic recording of patient monitor and anesthesia machine data and to facilitate intraoperative documentation of anesthesia care.[9,10] They improved the legibility and accuracy of anesthesia record keeping.[11–14] However, the real power of such systems is to analyze data to detect ongoing clinical issues or deviations from best practice protocols.[15–19] The operating room presents a critical and dynamic environment where rapid shifts in patient conditions are often encountered, and the anesthesia provider has to quickly process information from multiple sources and perform needed interventions to keep the patient physiologically stable. In such an environment, chances for oversights and errors are high.[20–26] Also, because of the complexity of anesthesia care and the rapid pace in an operating room, consistently following evidence-based care protocols is often difficult. A CDS system can help overcome these challenges. It can improve vigilance by processing AIMS and electronic medical record (EMR) data, detecting clinical issues, and notifying anesthesia providers so that remedial steps can be immediately taken. In addition, it can generate reminders and guidance messages to drive provider behavior toward evidence-based care. Other than the potential to improve patient safety and quality of care, CDS can also improve professional billing and reduce cost.

A prime example of the value of intraoperative CDS is in the treatment of unnoticed hypotension. Given that the duration of hypotension has been correlated to increased mortality,[27] multiple groups have established the ability to alert providers in real time of gaps in blood pressure (BP) monitoring[28,29] and unsafe BPs with the intention to reduce hypotension duration and severity and ultimately improve

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patient outcomes.[30,31] In another example, a CDS system targeting cardiac surgery was configured to alert providers that patient monitor alarms were not properly restored after returning to spontaneous circulation after cardiopulmonary bypass.[32] Other CDS systems have been applied for managing intraoperative glucose levels,[33,34] postoperative nausea,[35–37] and timing of antibiotic prophylaxis.[38–43]

Outside the scope of direct patient care, CDS has been applied to assist providers in adhering to quality measures, following department protocols, and completing documentation for billing and compliance needs.[44–53] CDS has been used to remind providers about departmental policies and pathways and to assist with protocol adherence when the system is able to identify target cases or candidate patients with pertinent comorbidities.[17,33,35,52,53] Furthermore, with the help of documentation reminders, CDS has been used to improve the yield of professional billing compliance and reimbursement.[45,46,48,51] Last, CDS has been used successfully to curb inhaled anesthetic waste by alerting providers when fresh gas flows become excessive.[19,54,55] Overall, CDS has great potential to be used for the development and implementation of perioperative quality improvement programs and to lead to the concept of digital quality improvement. (Digital quality improvement is the integration of information technology infrastructure into the quality improvement process, thereby leveraging the technological tools as a key part of the quality improvement implementation process. An example is the use of AIMS data and transaction logs from a medication dispensing station to improve reconciliation of controlled drugs.)[56,57] A comprehensive list of articles on AIMS and CDS can be found at http://www.FranklinDexter.net/Lectures/AIMSbibliography.pdf (Last accessed April 26, 2016).

Intraoperative CDS, especially real-time systems, continue to be an active area of research and development.[17–19] The use of individual CDS systems has been described widely in the literature. A few recent review articles have focused on describing the benefits of real-time CDS systems[17,18] and issues related to using AIMS data as feedback to influence provider behavior.[19] However, a comprehensive review of such systems, particularly the design and implementation considerations of intraoperative CDS systems, has not been published. Such a review is important because it will provide practicing anesthesiologists and administrators with a deeper understanding of the different types of intraoperative CDS and their relative benefits and weaknesses. It will also provide the anesthesia community guidance on design and implementation of these systems. In this article, we describe the different types of intraoperative CDS systems with specific emphasis on real-time systems. The technical and regulatory considerations when developing and implementing such systems, as well as ways to measure the efficacy of CDS systems, are described. Last, considerations for improvement and future development effort are outlined. A glossary of terms used in the article is presented in Table 1.

## CURRENT INTRAOPERATIVE CDS

### Types of CDS

Intraoperative CDS can be broadly classified as either passive or active. Passive decision support is triggered only when a provider initiates a predefined action. Typical examples are the "hard stop" feature in most AIMS that flags incomplete data elements when a provider tries to finalize a record and links in the AIMS system to review clinical protocols. Because passive decision support is triggered by user actions (finalizing a record, clicking a link), it can be useful only in instances where immediate action by a provider is not required when an unwanted event occurs. Furthermore, manual trigger means that, if the user fails to launch passive decision support, the user may be unaware of the undesired event, thus missing the opportunity to act in real time to correct the event.

Active decision support continually and automatically checks for issues without provider initiation. Active decision support can be either in nonreal time after a procedure is complete or in real time while a surgical procedure is ongoing. Non–real-time or post hoc decision support typically involves reports or e-mails after a case is complete with no notification generated at the time of the triggering event. Although these reports might not have direct impact for the affected patient, they can help reinforce pathways and policies aimed at reducing specific outcomes. Post hoc e-mail feedback has been used to communicate individual and group practice patterns on fresh gas flow settings in an attempt to change provider behavior to adopt lower fresh gas flows.[19] E-mail feedback has also been used to improve antibiotic delivery and timeliness of documentation.[40,58] Non–real-time decision support is simpler to set up. There is little or no risk of negative impact on AIMS operation. Also, the messaging mechanisms (typically automated e-mail reports) are nonintrusive for the anesthesia provider.

Real-time active decision support involves acquisition and processing of AIMS data to detect ongoing issues or deviations from best practice clinical guidelines. The goal is to bring the detected issues to the attention of the provider such that real-time remedial actions can be taken. Real-time systems are most effective in addressing patient safety and quality-of-care needs because corrective measures can be made immediately, thus impacting patient care directly. However, establishing a real-time decision support requires considerable technical skill and investment in securing real-time data, processing the data efficiently, and notifying providers in such a way that their attention is captured even in a busy operating room. This requires many considerations, such as data security, processing times, and transmission latency.[26] Although real-time systems can be complex, the upside is having a platform that allows for comprehensive decision support and protocol guidance. In such systems, data from multiple sources can be combined to create sophisticated and meaningful alarms.

The type of decision support to adopt depends on the problem in hand. Documentation errors or omissions that do not require immediate attention by the anesthesia provider are best addressed through passive decision support. Non–real-time active decision support is helpful in feedback of current provider performance and communicating steps for improvement. Active real-time decision support is most effective when real-time interventions on patient care are needed. To address a broad spectrum of needs ranging from patient safety, quality of care, billing, compliance, and waste reduction, it is very likely that all 3 types of decision

**Table 1. Glossary of Terms**

| Term | Description |
|---|---|
| CDS | Clinical decision support |
| AIMS | Anesthesia information management system |
| EMR | Electronic medical record |
| Thin Client | Workstation used to run AIMS application for a system configuration in which majority of the data processing is performed on a remote AIMS server. Typically, the workstation is used to establish a remote session on the AIMS server and very few clinical data are stored on the workstation |
| Thick Client | Workstation used to run AIMS application for a system configuration in which majority of the data processing is performed locally on the workstation. The thick client workstation stores a local copy of clinical data and periodically refreshes the data to a remote AIMS server |
| Passive CDS | CDS is passive until the user initiates it through a deliberate action such as clicking a link or button in AIMS. Decision aids such as clinical protocols or documentation errors are presented when the user performs one of the above actions |
| Active CDS | A CDS system that is actively checking for unwanted clinical events in an automated and continual manner. No user action is needed to trigger CDS |
| Post hoc CDS | An active CDS system that detects unwanted clinical events or documentation errors after a surgical encounter in a post hoc manner |
| Real-time CDS | An active CDS system that detects ongoing or impending unwanted clinical events in near real time during a surgical encounter |
| Reactive CDS | A real-time CDS system that detects ongoing unwanted clinical events after the events have occurred |
| Predictive CDS | A real-time CDS system that predicts unwanted clinical events before the events have occurred |
| Prescriptive CDS | A real-time CDS system that predicts unwanted clinical events and prescribes the best treatment option |
| Decision rules | Conditional logic interconnecting data parameters to detect a clinical event |
| Rules builder | A software module of the CDS system used to define decision rules |
| Data latency | Delays in data transmission and entry resulting in delayed availability of data for processing by a CDS system |
| Alert fatigue | A condition in which a care provider is exposed to excessive number of false alerts resulting in provider indifference to any alert |
| API | Application Programming Interface. A set of routines, protocols, and tools for building software applications. An API makes it easier to develop a software application by providing the needed building blocks. |
| FHIR | Fast Healthcare Interoperability Resources. A standard describing data formats, elements, and exchange of electronic health records |
| SMART on FHIR | A set of open specifications based on FHIR to integrate external software programs with EMR |

support are needed in an institution. Table 2 presents a comparison of the types of CDS systems and their relative advantages and disadvantages. Table 3 presents the main CDS systems described in the literature categorized into different types.

### Integrated and Stand-Alone CDS Systems

CDS systems can be either integrated with AIMS or stand-alone. Integrated systems are developed by AIMS or EMR vendors and built as part of their main AIMS products.[31,32,35,51] Stand-alone CDS systems work alongside AIMS as add-on modules. Typically, they are not developed by AIMS/EMR vendors and tend to be more focused on meeting the needs of the anesthesia specialist.[33,34,43,46,48,55] The advantages and disadvantages of these systems are outlined in Table 4.

## TECHNICAL CONSIDERATIONS FOR REAL-TIME CDS FOR ANESTHESIA

Unlike other areas of patient care, an operating room presents unique challenges to a real-time CDS system. The 2 primary challenges are (1) acquiring and processing high-velocity, often high-volume data accurately and efficiently in real time and (2) capturing the attention of the anesthesia provider in a complex and dynamic environment. Technical considerations for designing and developing a real-time CDS system should address the above challenges.

### Components of an Intraoperative CDS System

The main functional components of a basic intraoperative CDS system are shown in Figure 1. A data acquisition module interfaces with AIMS and other hospital information systems to acquire pertinent data for the CDS system. A data translation layer would process and normalize the data to a standard data dictionary. A set of predefined decision rules are then applied on the normalized data to either generate guidance reminders or detect ongoing issues. A messaging module generates notification messages to convey alerts and reminders to the anesthesia providers. Depending on how the CDS system is implemented, some of the functional modules could be integrated and be part of AIMS. For a stand-alone CDS system, these functional modules would be independent of AIMS.

### Data Acquisition: Real-Time Data

The availability of real-time data is critical to perform immediate guidance and detection of issues. Data latency or delayed availability of data has 2 main ill effects.[59] First, nonavailability of real-time data means delayed detection of ongoing clinical issues. Second, data latency could result in false-negative notifications, whereby CDS notification of clinical issues is presented after an adverse clinical event has either been noticed or resolved by the anesthesia provider. False-negative notifications result in inaccurate presentation of issues, user annoyance, and poor user acceptance of decision support.

Data latency could be attributable to several factors.[59,60] Delays in refreshing the AIMS database with the most current data are one. This is particularly problematic in an AIMS configuration that uses a thick client. In a thick client configuration, the majority of the data acquisition and processing occur in an AIMS workstation at the site of anesthesia care. The AIMS workstation (thick client) periodically

**Table 2. Comparison of Different Types of CDS**

| Type of CDS | Advantages | Disadvantages | Typical Implementation Examples |
|---|---|---|---|
| Passive CDS | • Simple solution, typically easy setup, and maintenance<br>• Easily integrated into AIMS<br>• No interference with provider interactions with AIMS<br>• No impact on AIMS operation | • Limited capabilities<br>• Cannot provide real-time guidance<br>• Limited ability to change provider behavior<br>• Can address only simple, "static" issues | • Links to clinical guidelines<br>• Configuration of data element as required for closing anesthesia records in AIMS |
| Post hoc active CDS | • No need for real-time data<br>• No interference with provider interactions with AIMS<br>• No impact on AIMS operation<br>• Simpler development and maintenance when compared with real-time systems | • Cannot provide real-time guidance<br>• Limited ability to improve patient safety as real-time detection of adverse events cannot be performed<br>• Lesser ability to change provider behavior than real-time systems | • Next day report on incomplete and open records in AIMS<br>• Feedback reports on provider practice patterns<br>• Daily report of postoperative complications |
| Real-time active CDS | • Can provide real-time guidance to comply with evidence-based, best practice guidelines<br>• Ability to improve patient safety because of real-time detection and notification of adverse events<br>• Ability to change provider behavior<br>• More impact on patient outcome | • Requires real-time data<br>• Complex system and higher maintenance requirements<br>• Potential to create alert fatigue in providers<br>• Potential for interference with provider interactions with AIMS<br>• Risk of negatively impacting AIMS operation | • Real-time alerts for unwanted clinical scenarios (eg, hypotension and high inhalation agents)<br>• Real-time guidance for glycemic management<br>• Real-time assessment of PONV risk and guidance for PONV prophylaxis |

Abbreviations: AIMS, anesthesia information management systems; CDS, clinical decision support; PONV, postoperative nausea and vomiting.

submits local data to a remote AIMS database at a predefined interval. The longer this interval, the greater is the data latency. Slow data sampling is a second source of data latency. Data sampling pertains to how frequently a CDS system samples the AIMS database to acquire clinical data. If the CDS system is an add-on module, factors such as nontrivial data extraction time and potential negative impact of real-time data extraction on the AIMS operation could limit how frequently the CDS system can acquire data from the AIMS database. Data sampling also pertains to sampling of medical device (patient monitor, ventilator, etc) data by the AIMS system. Slow sampling of patient monitor data by AIMS could not only result in failed capture of transient, yet critical changes to a patient's hemodynamic status, but also result in delayed availability of medical device information in AIMS and CDS systems. Although data sampling of medical device data is generally configurable in most AIMS, interface and data storage constraints generally limit data sampling intervals to every 15 seconds to 1 minute depending on the AIMS system. Non–real-time interfaces are another source of data latency. Laboratory and blood bank interfaces are typical examples. Sometimes these interfaces may depend on manual entry of results or completion of patient registration information to transmit results to AIMS. If the laboratory technician is busy or if patient registration is incomplete during emergency cases, the information transmitted through these interfaces may be delayed. Finally, retrospective manual entry of data into AIMS by the anesthesia provider is also a source of data latency.[60]

Eliminating data latency is difficult, but steps can be taken to minimize it. A thin client configuration of AIMS in which data are stored directly in a central database rather than having local copies on a workstation helps minimize data latency. Frequent sampling of data directly from the medical devices to the CDS system eliminating the intermediate AIMS system will ensure immediate availability of hemodynamic and ventilation parameter data. Automation of data entry would allow near real-time data for CDS systems and minimize delays associated with manual retrospective data entry. For example, automated drug documentation through barcode and optical technology (BD Intelliport Medication Management System; Becton Dickinson and Company, Franklin Lakes, NJ) and integration of infusion pump data into AIMS and CDS are ways to eliminate manual documentation of these data.

## Impact on Production AIMS

A CDS system that works alongside AIMS must not negatively impact AIMS operation or impede the basic record-keeping function of AIMS. Hence, any real-time, high-frequency data acquisition from AIMS should be performed with care. The use of a shadow database that mirrors the production database in real time would allow isolation of CDS data acquisition, protecting normal AIMS operation. However, setting up a real-time shadow database that contains all the data needed for the CDS system is often a challenge and is dependent on the AIMS/EMR system configuration and capability. If replication of data in the shadow

**Table 3. Classification of Intraoperative CDS Initiatives Described in the Literature**

| | Target Item | CDS Description |
|---|---|---|
| Passive | Billing/compliance | • Required fields or hard stops in most AIMS to ensure completion of documentation related to billing and compliance (no pertinent studies in the literature) |
| | Clinical protocols | • Links to clinical protocols from AIMS (no pertinent studies in the literature) |
| Active: Post hoc | Quality measure | • E-mail report on timely antibiotic administration[40,42] |
| | Billing/compliance | • Individualized e-mails highlighting noncompliant documentation (emergence documentation before end of procedure)[58] |
| | Cost savings | • Individualized feedback on gas flows in an educational attempt to reduce excessive gas flows and save inhalation agent use[19,54] |
| Active: Near real time | Quality measures | • Alerts for timely antibiotic initial dose and subsequent redoses[38,39,41–43] |
| | | • Notification to document perioperative β-blocker administration[51] |
| | Billing/compliance | • Notification concerning incomplete documentation of invasive lines if corresponding blood pressures are detected[45,48] |
| | | • Notification concerning incomplete or incorrect data elements required for billing[46,51] |
| | Patient monitoring/anesthesia management | • Notification when there are gaps in noninvasive blood pressure monitoring[28,29] |
| | | • Notification when hypotension or hypertension is encountered[30,31] |
| | | • Alert to activate patient monitor alarms after cardiopulmonary bypass[32] |
| | | • Recommendation on tidal volume for patients at risk of acute lung injury[52] |
| | Clinical protocols | • Reminders to adhere with glycemic management guidelines—regular glucose measurement and initiation of insulin when hyperglycemia is encountered[33,34] |
| | | • Feedback on PONV risk and antiemetic drug therapy[35–37] |
| | Cost savings | • Feedback on fresh gas flow setting with recommendation to reduce gas flows and inhalation agent consumption[55] |

Abbreviations: AIMS, anesthesia information management systems; CDS, clinical decision support; PONV, postoperative nausea and vomiting.

**Table 4. Comparison of Integrated and Stand-Alone CDS Systems**

| | Advantages | Disadvantages |
|---|---|---|
| Integrated | • CDS solution self-contained within the AIMS product | • Features and capabilities tend to be broad |
| | • Immediate access to AIMS data with minimal data latency | • Lack of specialization and focus to meet the specific needs of anesthesia |
| | • Seamless adaptability to AIMS configuration and version changes | • Simplistic, inflexible solutions poorly customized for anesthesia needs |
| | | • With larger EMR vendors, slower pace of enhancements to CDS features |
| Stand-alone | • Decision support features and capabilities generally superior | • Direct access to AIMS data may not always be feasible, which can compromise real-time decision-making capabilities |
| | • More customized to meet anesthesia needs | • Needs to keep up with updates to the primary source systems (AIMS and EMR) to prevent data interface failures |
| | • Generally, faster pace of enhancements | • Requires more maintenance |

Abbreviations: AIMS, anesthesia information management systems; CDS, clinical decision support; EMR, electronic medical record.

database is delayed, it will introduce data latency in the CDS system. Interrogating the production AIMS database directly will ensure minimum data latency and access to a broader data set for the CDS system. However, low impact database queries (eg, "no lock" clause in SQL queries) should be used to ensure that AIMS database transactions are given priority when compared with CDS queries. In addition, consideration should be given to how frequently data can be sampled from the AIMS/EMR database, with no impact on AIMS/EMR operation. Higher data sampling, although desired for early detection of adverse events, could potentially impact AIMS performance. An approach utilizing multiple sampling rates whereby less dynamic data parameters are sampled less frequently when compared with more dynamic parameters could reduce the risk of affecting AIMS operation while providing meaningful real-time data.

Recent developments in improving interoperability of EMR data are leading to new standards by which the AIMS/EMR companies can make real-time clinical data available to external applications such as a stand-alone CDS system. An example is Fast Healthcare Interoperability Resources (FHIR), a standard describing data formats and elements and an application programming interface for exchanging electronic health records (FHIR Standards. Available at: http://www.hl7.org/implement/standards/fhir/. Last accessed April 9, 2016). Furthermore, SMART on FHIR platform, a set of open specifications based on FHIR, to integrate external software program such as CDS with EMR is being developed (SMART. Available at: http://smarthealthit.org/. Last access July 21, 2016). By allowing the AIMS/EMR vendors to make real-time data via FHIR, the risk of an external program potentially impacting the performance of AIMS is eliminated. Also, it helps to keep the data interface of the CDS system agnostic of the AIMS/EMR system differences and version changes. However, FHIR standards are still immature, and additional work, including increased support and development from EMR vendors, needs be completed before they can be used to obtain comprehensive real-time data for CDS systems.

## Data Processing

Raw data acquired from AIMS and other sources are generally not in a format suitable for decision rules to be readily

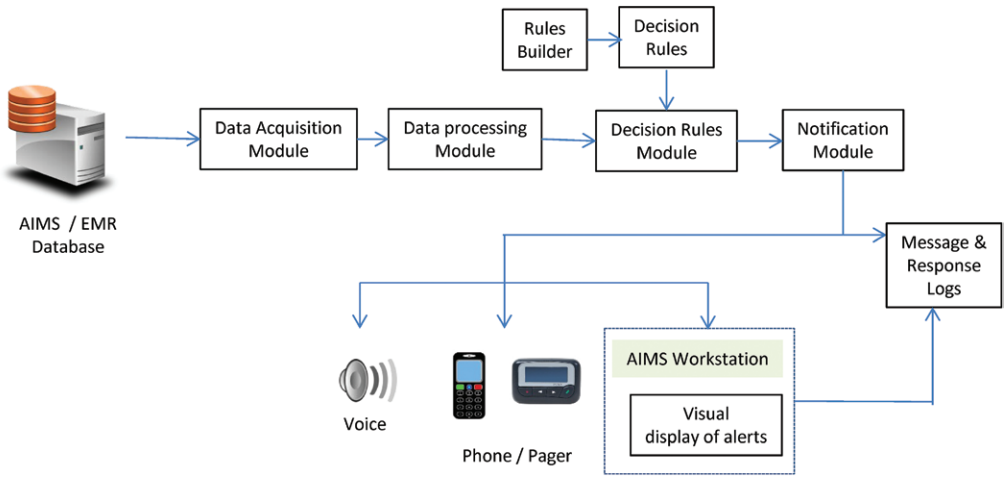


**Figure 1.** Main components of an intraoperative real-time clinical decision support system. AIMS indicates anesthesia information management systems; EMR, electronic medical record.

applied. Data processing involves transforming the raw data, filtering artifacts, computing dependent parameters, and estimating missing data. For the CDS system to have wider applicability, it is essential that the data acquired from disparate AIMS and EMR systems be normalized to a standard CDS data dictionary. Adopting a standard data dictionary would allow a CDS system to build only data acquisition interfaces for it to integrate with AIMS. Then, the subsequent decision logic module and the decision rules can remain standardized and globally applicable independent of the source AIMS/EMR systems.

Filtering artifacts, particularly in medical device data, will minimize the risk of unanticipated and incorrect outcomes when applying decision logic. Filtering nonphysiologic out-of-range values would be a straightforward and simple approach. Alternately, more sophisticated methods can compare multiple or multisourced parameters to identify artifacts.[61] For example, the fact that diastolic, mean, and systolic BPs should be in increasing order can be used to validate BP measurement. A lack of correspondence between pulse rate derived from plethysmography and heart rate derived from electrocardiography could be used to detect artifacts in the heart rate parameter.

Data processing would also involve computation of derived parameters not available in the source systems. Examples include age-adjusted minimum alveolar concentration, BP targets based on patient age and surgical procedure, and total fresh gas flow. These derived parameters can also be part of the CDS data dictionary. If algorithmic decision support is implemented, data processing will involve computation of additional parameters based on the algorithm. For example, if a glycemic management algorithm is implemented, then the processing module would have to compute the recommended insulin dose based on the glucose values. Similarly, decision support for postoperative nausea and vomiting (PONV) prophylaxis would require that the CDS system compute the PONV risk factor.

AIMS or EMR data can be imperfect, sometimes missing information. The methods used to handle missing data in a CDS system depend on how critical the data element is and how frequently data are missing. If the data element is either not critical or only missing occasionally, then no action may be needed. However, if the element is critical and missing often enough to impact decision support, statistical methods may have to be adopted to estimate the missing data. An example would be the computation of PONV risk factor when the smoking status of the patient is missing. In such instances, imputation statistics could be used to estimate the smoking status from other procedure- and patient-related parameters.[62,63] Imputation statistics are developed using retrospective AIMS and EHR data to arrive upon an estimation algorithm for missing data. The estimation algorithm would then need to be programmed as part of the data-processing module to impute the missing data value.

## Decision Rules Module

Decision rules are the brains of the CDS system. Two functional components need to be considered to define rules a priori and execute them in real time.

The first component is a rules builder module that gives the ability to construct the decision logic. Decision support logic generally gets modified over time based on user feedback, results from data analytics, and changing practice patterns. To accommodate this continuous refinement of decision logic, the CDS system should be flexible and adaptable. For this reason, it is best not to hard code the decision logic into CDS software program making it difficult to change. A separate rules builder module capable of easily establishing and modifying decision rules becomes very useful. Functionally, the rules builder should be capable of combining parameters in the CDS data dictionary using arithmetic and comparison operators and then defining Boolean logic for the decision rules. The rules builder should also be able to prioritize rules, compose notification messages, and configure the notification modality. The decision rules defined through the rules builder should ideally be saved in a structured and standard format that allows sharing of rules between institutions and systems. Many AIMS products, especially those that are part of EMR systems, do not have a decision rules builder for perioperative decision support, but rather have a limited set of decision rules hard coded in the AIMS software. However, stand-alone AIMS or CDS

commercial systems (eg, Advanced Clinical Guidance, Talis Clinical, Cleveland, OH, and AlertWatch, Ann Arbor, MI) and noncommercial CDS systems that grew out of academic institutions (eg, Smart Anesthesia Manager, University of Washington, Seattle, WA, and iKnow, University of British Columbia, Vancouver, BC) have rules builder modules tailored for anesthesia and perioperative setting. Examples of some rules builder modules are shown in Figure 2.

The second component is a module that can execute the decision rules in real time. This involves reading and parsing the decision rules established by the rules builder and applying them on the CDS clinical data to detect impending or ongoing clinical issues. The execution of decision rules should not only be done accurately but also quickly and efficiently. Quick execution of rules is particularly important for a centralized CDS system that serially processes data from all active procedures one by one to detect issues. If the system requires a significant amount of time to process data and execute rules for each active procedure, the cumulative time taken to process all active procedures may become substantial. This in turn will limit how frequently the CDS system can sample the AIMS/EMR, thus contributing to increased data latency. Hence, efficient software code that can execute decision rules quickly is critical. However, as the CDS system capabilities grow, and more and more decision rules are built, or if the CDS system is implemented in an institution with a large number of active operating rooms, it may not be possible to reduce rules execution time

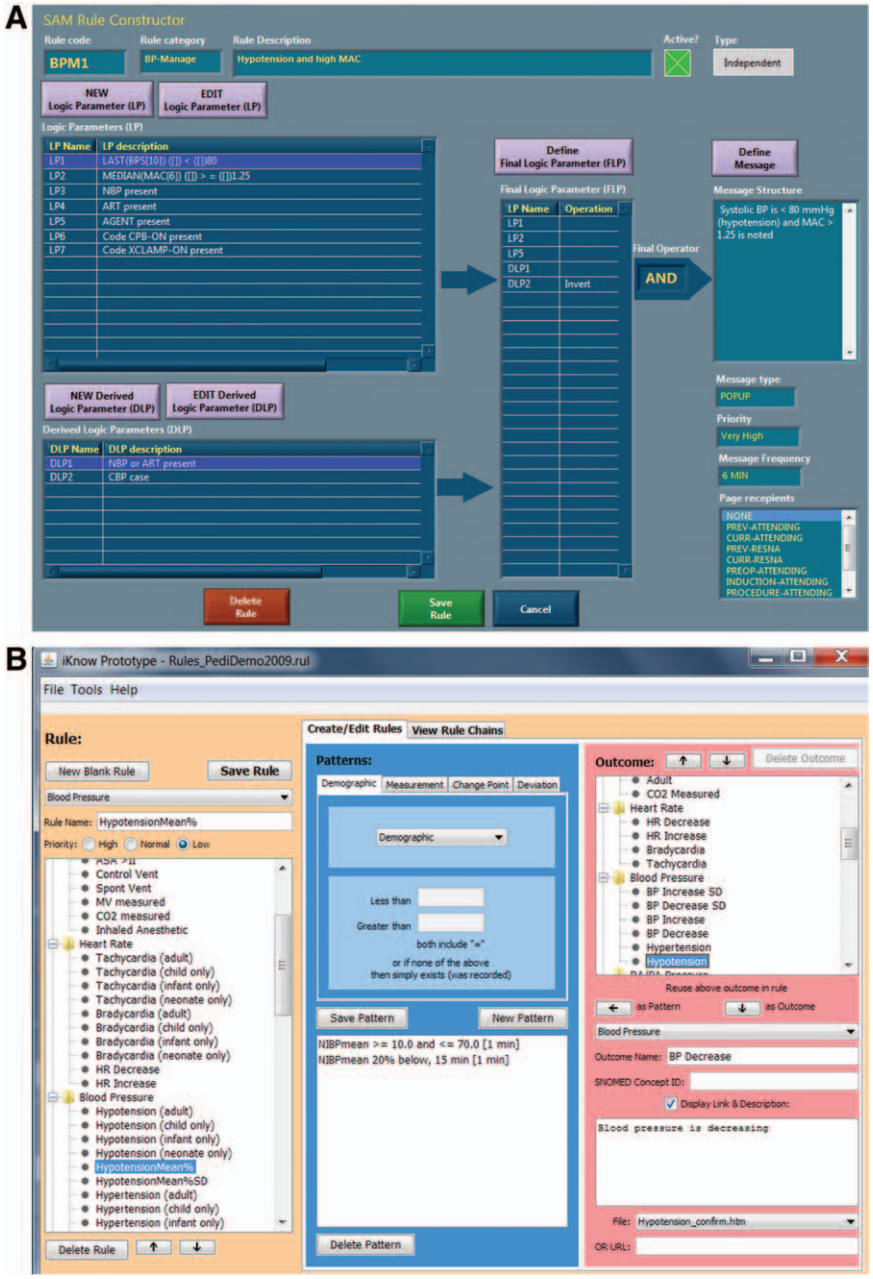


**Figure 2.** Rules builder modules in (A) Smart Anesthesia Manager (SAM) and (B) iKnow clinical decision support systems.

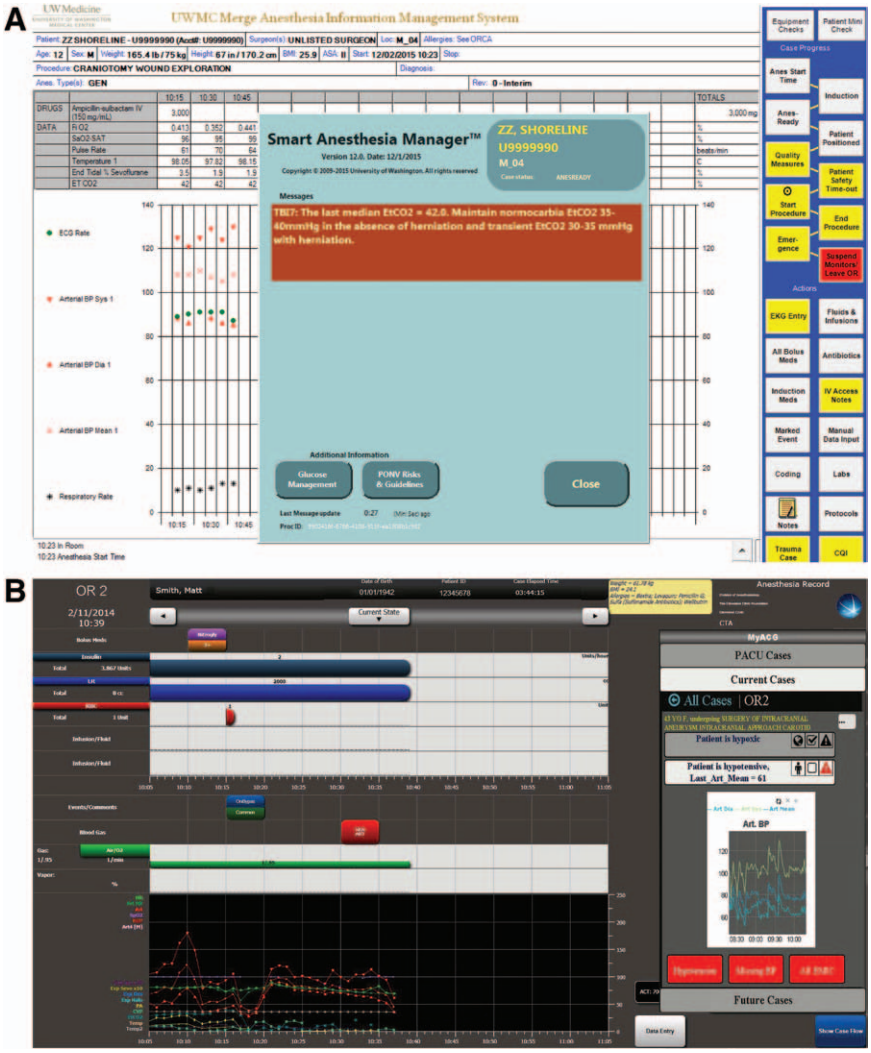


**Figure 3.** Clinical decision support notification screens in (A) Smart Anesthesia Manager and (B) Advanced Clinical Guidance developed by Talis Clinical Inc.

if serial processing is adopted. Under such scenarios, the system configuration may have to resort to parallel processing techniques to minimize the software execution time.

## Alert Notification Module and Methods

Notification of issues and capturing the attention of the anesthesia provider are significant challenges in a busy, noisy operating room full of distractions from various device alarms. Real-time CDS systems have traditionally used text pages or visual means such as popup messages or blinking buttons on the AIMS computer screen to notify anesthesia providers concerning clinical issues (Figure 3).[17,19,31,47,48] Alternately, AlertWatch Inc uses a novel visual display of organ systems with a combination of color codes and textual description to present alerts (Figure 4).[34]

E-mail has also been used for notification if real-time attention is not needed.[19,40,58] Voice feedback has been used as notification method for medication administration,[64] although it has not been used as a notification mechanism for intraoperative CDS systems. Voice or audio feedback holds promise for alerting critical events especially in the operating room when the often busy anesthesia provider may not always be watching the AIMS computer screen to see a visual display of the alert. Tactile stimulation has been tried to capture the attention of anesthesia providers for critical events in the operating room with some success.[65,66] However, thus far, this interesting notification modality has not been tried with CDS systems.

A critical requirement is that the notification messages reach the correct anesthesia providers. Text messages and e-mail should be directed to specific providers, whereas visual and audio notifications should be targeted to the correct computer workstation (likely an AIMS computer) in the correct location where active anesthesia care is occurring. Targeting the correct workstation is often a challenge in thin client AIMS configuration that does not require tracking the specific workstation used for anesthesia record keeping. In such instances, knowing which workstation is actively used for anesthesia care becomes difficult. Associating a procedure location with an AIMS workstation may not be reliable as the anesthesia machines with the AIMS computer could get moved from one operating room to another. A more reliable option would be to utilize the patient monitor mapping information to associate workstations. Because the patient monitor, anesthesia machine, and the AIMS workstation

form 1 unit, the map between the patient monitor and workstation is unaffected if the operating room location is changed. An even more reliable mechanism would be to use a notification tool (eg, "Discern Notify" tool in Surginet Anesthesia Information Management System; Cerner Inc, North Kansas City, MO) made available by the EMR/AIMS vendor that is integrated as part of their product.

Presentation of the CDS alert message should capture the attention of the provider, whereas the message itself should clearly explain the issue and suggest guidance to resolve the issue. However, the display of the alert message should not impede user interaction with AIMS or obstruct the display of AIMS data. This is particularly a concern with stand-alone CDS systems that operate independent of AIMS. A stand-alone CDS is often unable to track a provider's interaction with AIMS, and, hence, notification messages may pop up when the provider is actively entering data into AIMS. Hence, the priority of an alert and the need to display it prominently to capture attention should be weighed against potential interference with user interaction so that the best clinical outcome can be achieved. Color codes to highlight the priority of alert messages could help the users differentiate which alerts need immediate attention and which ones do not. Although different mechanisms to present alerts have been used, human factor design considerations[67] have been poorly studied in the context of intraoperative CDS systems.

Repetition of an alert may be needed if a clinical issue continues and the provider has not responded. However, how frequently a message needs to be repeated should be balanced against the potential for alert fatigue. Also, it is possible that the anesthesia provider is unable to respond to the clinical issue or that the alert is not applicable in a certain scenario. Issuing alerts in such instances will contribute to user annoyance. The CDS system should allow the provider to disable an alert if not applicable. Although multiple groups have studied distractions caused by patient monitor alarms,[68–70] alert fatigue caused by a CDS system in the operating room is yet to be rigorously studied.

### Logging CDS Alert Messages and Provider Response

The CDS system should be able to log the alert and guidance messages that it has issued. This should include the case information, the time of the alert, the alert message, and the recipient provider or workstation. In addition, the system should log the provider responses to the alerts; specifically, the time when a message was acknowledged or whether the provider disabled an alert. Logging alert messages and provider response is useful for retrospective analysis to determine the efficacy of the CDS system. The logs should primarily be used for quality improvement purposes, to evaluate whether notification messages were generated and delivered correctly and whether the user received the message. These logs may be discoverable in legal disputes unless protected by federal or state laws.

### Testing and Validation

Testing and validation of the CDS system and decision rules are critical steps before implementation. Test scripts should be prepared to test each condition of a decision rule. Testing in a nonproduction environment using simulated data is the most straightforward step toward validation. However, simulations cannot replicate the actual operating room environment and anesthesia data. A test environment that allows retrospective playback of actual AIMS records could be used to more realistically test a CDS system. An alternate possibility is to test the CDS system on the production AIMS system, but without actually delivering the alert messages. This "silent" testing allows monitoring and validation of the system using actual case data without impacting users. Documentation of test results including expected and observed results along with evidence (screen prints, video recordings, etc) and witness signatures should be stored in a quality management software to comply with good software validation practices (General Principles of Software Validation; Final Guidance for Industry and FDA Staff. Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf. Last accessed April 9, 2016).

### Handling Unexpected Events and Outcomes

Last, a CDS system should be designed to minimize the risk of unexpected outcomes and unanticipated actions by the anesthesia provider who is receiving decision support. Unexpected outcomes may include failure of the system to issue an alert, either because of software error or corrupt data. Unanticipated actions may be because of the anesthesia providers misunderstanding an alert message or acting on the basis of a wrong alert. Having filters to remove artifact data and careful design of decision logic are steps that should be taken to minimize the risk of unexpected events and outcomes. Furthermore, the system should also provide a provision for the anesthesia providers to report incorrect or missed alerts. Soliciting user feedback through surveys and focus groups and retrospective analysis of CDS data could highlight system deficiencies that can be used to correct software defects and iteratively refine the CDS system.

## REGULATORY CONSIDERATIONS

Although CDS systems can improve patient care and safety, they carry the potential risk of harming a patient.[71,72] The risk for harm depends on the decision support features and intended use of the CDS system. In relation to intraoperative CDS, neither decision support addressing billing, compliance, and documentation issues, nor non–real-time CDS that alerts after the end of a procedure poses any harm to the patient. Only an active real-time CDS system that addresses clinical care items has the potential risk for harm.

Potential harm for a patient can occur if a wrong alert is issued thereby triggering an anesthesia provider action that compromises patient safety. Wrong alerts could result from software defects, logic errors in decision rules, or data artifacts. For example, if there is a software defect that mistakenly processes mean BP instead of systolic BP, hypotension alerts would be wrongly triggered. As another example, if an arterial BP waveform is damped resulting in BP measurements being artifacts, false hypotension alerts could be triggered. Potential harm can also occur if an expected alert is not generated. For example, if a software error prevents

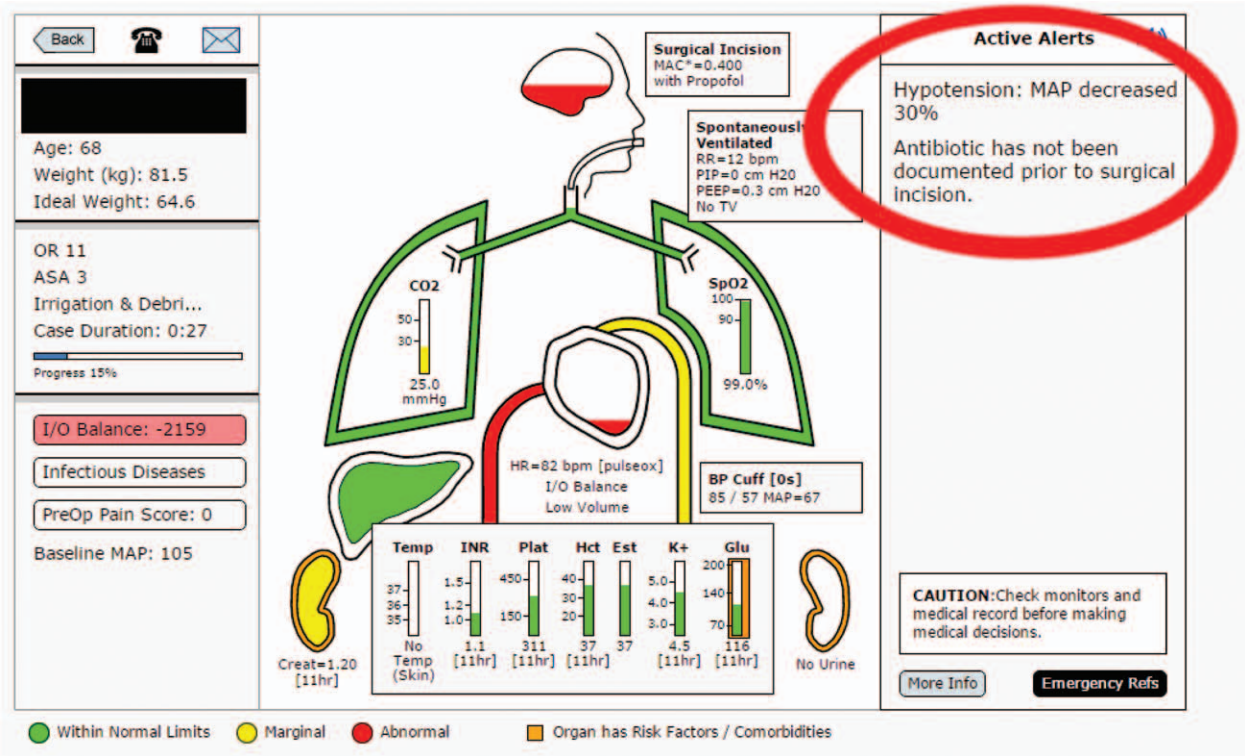


**Figure 4.** Clinical decision support notification in AlertWatch. ASA indicates American Society of Anesthesiologists; BP, blood pressure; OR, operating room; INR, international normalized ratio; MAP, mean arterial pressure; PEEP, positive end-expiratory pressure; PIP, peak inspiratory pressure; RR, respiratory rate; TV, tidal volume.

a reminder alert for glucose monitoring from firing, glucose levels may be left unmonitored. Concurrently, if an insulin infusion is ongoing, this scenario may pose an increased risk of hypoglycemia. Similarly, failure to trigger antibiotic reminders can cause a missed antibiotic redose, thus compromising quality of care.

CDS systems may be subject to regulation based on intended use and risk for potential harm. The Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012 required that 3 agencies, the Food and Drug Administration (FDA), Federal Communications Commission (FCC), and the Office of National Coordinator for Health IT (ONC), work together to jointly produce a report detailing the strategy and recommendations for a health IT framework. The report produced in 2014 describes a more deregulatory approach by these agencies (FDASIA Health IT Report (2014). Available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf. Last accessed April 9, 2016). The report cited that the FDA does not intend to oversee most CDS because the potential benefits outweigh risks. The report states that only a limited set of CDS systems that pose higher risk would have FDA oversight. However, the report is ambiguous on the actual criteria to decide whether a CDS product is regulated or not.[73]

In parallel, legislation related to CDS has been introduced. Bills in Congress, SOFTWARE (Sensible Oversight for Technology Which Advances Regulatory Efficiency) Act, and in the Senate, PROTECT (Prosecutorial Remedies and Other Tools to End the Exploitation of Children) Act, aim to further deregulate, making the majority of CDS free of regulation. The SOFTWARE Act proposes a risk-based regulatory framework using 3 software categories—medical software that aids diagnosis, thus posing the highest risk, clinical software that informs care steps, and health software that targets efficiency of administrative tasks. Only medical software that treats patients directly without physician involvement would be subject to regulation. The PROTECT Act further reduces FDA oversight on CDS, with supervisory authority placed on National Institute of Standards and Technology (NIST), a nonregulatory agency. Internationally, European Union (EU) and Medicines and Healthcare Products Regulatory Agencies (MHRA) have released guidance statements that parallel that of the FDA. Overall, the regulatory framework concerning CDS is in a state of flux, and the government agencies, such as the FDA, have been slow to issue meaningful guidance on CDS regulation.[19,73]

Regulatory oversight may vary depending on the nature of the implementation, whether a home-grown CDS system is used locally in the hospital system versus a commercially marketed system.

## Local Implementations for Quality Improvement

Local implementation refers to development and use of a CDS system to meet the specific needs of an institution. Such systems are the ones most frequently described in the literature and can be used for items as diverse as assisting with timely antibiotic administration,[42] billing compliance,[17,45] and glycemic management based on institutional guidelines.[33] In such a situation, governmental

regulatory approvals are likely not needed. Instead, institutional risk management and IT security groups could provide approvals for use and guidance on risk mitigation strategies. Furthermore, departmental oversight through a committee that decides which decision support rules and strategies to adopt may be needed. Such an oversight committee can ensure that the problem being addressed by the CDS is valid, the decision support strategy is well defined and applicable to the local hospital system, and the proliferation of CDS alerts that can potentially overwhelm providers and decrease adherence is limited.[74,75]

### Clinical Decision Support for Research Purposes

If a CDS system is used to study a research hypothesis or explore a research question, the regulatory requirements are different from those of quality improvement initiatives. In these instances, the requirements of the local institutional review board (IRB) must be met. The relevant questions for the IRB generally involve the safety of the participants in the study, which can be both the patients and the providers being studied. Depending on the risk, the IRB may require that an investigational device exemption be obtained from the FDA.

### Commercial Decision Support Systems

Commercial CDS products (eg, AlertWatch[76]), if considered a "medical device," may be subject to federal regulation by the FDA. Key factors that determine the appropriate classification for the CDS system for regulation would be (1) the intended use of the CDS system, (2) whether the system makes therapeutic recommendations, and (3) whether the anesthesia provider is substantially dependent on the system to make diagnosis or treatment decisions.[73] The FDA has used substantial dependence as a criterion to differentiate regulated software from unregulated. Substantial dependence is determined based on (1) transparency of CDS recommendations, so that the anesthesia provider has enough information to evaluate the contributing clinical factors and logic; (2) competency of the provider using the CDS to independently make the clinical decision; and (3) sufficiency of time to evaluate and consider the CDS recommendations. If the CDS data input and recommendations are transparent to the provider, the provider is competent to interpret the recommendations and has sufficient time to consider and act, the provider is not substantially dependent on the system.

It should be noted that decision rules cannot be separated from the CDS system for regulatory approval. Wrong alerts can result not only from poorly constructed decision rules but also from software defects in the CDS program that executes the rules. Hence, if risks warrant regulation, the entire system—the software and the rules together—would be considered for regulatory oversight. Regulatory agencies have shown particular concern for how a device deals with errors. Agencies would expect the system to log all internally detected errors, as well as provide a mechanism for users to report errors. In addition, the CDS vendor must have a system in place to handle these errors and correct them in a timely manner.

## MEASURING EFFECTIVENESS OF CDS

Critical to CDS system, implementation is the quantification of its success. Measuring the effectiveness of a CDS system can be broadly classified into the following categories:

### Performance Measures

CDS performance measures are the most fundamental, essentially assessing the accuracy and specificity of the alerts. Accuracy measures the ability of the decision logic to detect the actual clinical events targeted by the CDS. It measures the proportion of time alerts that are triggered when true clinical events occur. Specificity measures the ability of the CDS system to differentiate actual clinical events from false events. Although ideally 100% accuracy and specificity are desired, data latency, artifacts, software defects, data interface changes, and poorly constructed decision rules could all contribute to alerts not triggered for true events and false alerts triggered when there is no event.[77]

### Process Measures

Process measures assess the direct effect of CDS on provider behavior. They measure how closely the provider response matched the desired response recommended by the CDS. For example, if the CDS reminds providers for timely administration of antibiotics, the process measure would be the compliance to timely antibiotic delivery by the anesthesia provider. Similarly, a system that provides decision support for glycemic management could measure compliance to institutional glucose management protocol to gauge success of the CDS system. Most studies[17,33,34,50] on intraoperative CDS systems have focused on process measures to assess system effectiveness.

Providers may fail to act on CDS alerts for a variety of reasons. The provider may simply not see an alert if he or she is either distracted or busy with clinical care. Alternately, the provider may misinterpret an alert or recommended action if the message is unclear. Yet, another reason could be that the alert is not pertinent to a clinical situation. When assessing CDS effectiveness through process measures, consideration should be given to analyze the reasons why providers failed to respond to alert messages. Steps can be taken to capture the reasons for provider's lack of response to CDS alerts. An acknowledge button on the CDS message screen could be used to verify that the provider saw the alert message. In addition, a data field in the alert screen or in AIMS can be configured to let the provider document the reason why an alert by the CDS system was ignored.

### Outcome Measures

The ultimate goal of the CDS system is to improve patient outcome. Hence, the goal of a CDS system targeting close adherence to a specific protocol such as glycemic management should not only be improved compliance to these protocols but also improved glycemic levels or, even more boldly, a decrease in postoperative wound infections. Similarly, when evaluating a CDS targeting PONV prophylaxis, not only should compliance to PONV prophylaxis guidelines be measured, but also the actual occurrence of postoperative nausea with and without CDS. In general, very few studies have tied patient outcome with CDS, and

the literature has failed to find consistent evidence that these systems have improved outcomes.[78] The reason that these outcome measures are so difficult to associate with decision support tools is that they are often multifactorial. For example, normal intraoperative blood glucose not only is the result of checking a blood sugar and starting insulin, but it is also based on patient responses to systemic stress and metabolic factors and the efficacy of the algorithm used for glycemic management. Often a single intervention such as decision support is generally insufficient to change a complex outcome parameter.

### Uptime Measure

System "uptime," or the time period when the CDS system is reliably operating, is critical for its success. Downtime can occur because of software defects that result in the CDS program being unresponsive. Downtime could also be a result of computer system and security updates or even other reasons such as accommodating daylight savings time change. Clearly, systems that are down cannot deliver alerts; hence, it is important to know the percentage of time the system is up and running and whether downtime events are scheduled or unanticipated.

### Alert Fatigue

The detrimental effects of alarm fatigue on clinicians have been studied previously in the context of patient monitors.[68–70] Frequent firing of audible or visual alarms by the patient monitor has been shown to cause provider distraction and indifference to alerts.[68,70] Similarly, a CDS system could also create alert fatigue[74,75] that can cause providers to disregard its messages. Even worse, alerts that are poorly timed (such as an alert for correcting a minor administrative issue during an airway emergency) can actually impede provider workflow. Indirect measures of alert fatigue could be obtained through analysis of CDS alert logs to determine the number and frequency of alerts that were delivered. Alert dwell, the time from generation of an alert to its acknowledgment, has also been studied as a measure of alert fatigue in the context of CDS.[79] Alternately, surveys and focus groups can be used to solicit feedback from providers on alert fatigue.

### User Acceptance

User acceptance is critical to the success of a CDS system. This pertains to the decision support strategy, the alert or guidance messages, and the mechanism by which the messages are delivered. If there is lack of unified consensus on a clinical guideline, providers may not heed CDS alerts and reminders pertinent to the guideline.[33] Similarly, if alert triggers and messages are unclear, provider acceptance will be low. Also important is the alerting mechanism. If the alerts are in the way of patient care, they may prove to be annoying and likely ignored. As Cho et al[80] report, different providers respond to alerts differently and with different rates. Thus, effective systems may need to tailor their alerts to the providers' personal preferences. Carefully constructed surveys and focus groups could be used to assess user acceptance of the CDS system and to determine reasons for poor acceptance.

### Improving CDS Systems

Decision support systems, like any technology tool, should be subject to continuous improvements and modifications. As the technology changes, upgrades should be made to decrease downtime and improve accuracy. Even more important, systems should take into account the feedback from the end users to make refinements to the decision support strategy and system features, thereby increasing their effectiveness.

## FUTURE CONSIDERATIONS

Although alarms simply notify that a parameter from a single monitor is outside a set range, messages from a clinical decision support system are generated from the combined information from multiple sources, such as monitors and electronic health care record. Still, current CDS systems are reactive in nature. Clinical issues and deviations from clinical protocols are detected after the fact and brought to the attention of the providers after an event has already occurred. Instead of reactive decision support, the possibility of providing predictive decision support to prevent adverse events would be an attractive possibility. The potential exists for a CDS system to serve as an early warning that a dangerous situation may be developing and to provide immediate helpful information during a crisis. For example, a moderate increase in heart rate with a slowed upstroke of the capnogram waveform and a moderate decrease in BP in a patient given an antibiotic a few minutes earlier may give warning of an impending anaphylactic reaction. These fairly subtle clues from a variety of sources may provide warning minutes before cardiovascular collapse or inability to ventilate because of severe bronchospasm. The message derived from the pooled information would be much more helpful and pertinent than individual alarms noting increases or decreases in single physiologic parameters. Another example of combining information from multiple sources is sudden drop in BP, a possibly dangerous situation, but when associated with sudden drop in end-tidal carbon dioxide is a situation that could be much worse. In addition, the clinical decision support system could communicate the likelihood of hemorrhage, air embolism, or other critical incidents associated with the ongoing procedure. Furthermore, the system could display the most important steps in treating the crisis.

To fully realize this potential of predictive decision support, rules used by the CDS system must quickly integrate the information from multiple monitors. Currently, most CDS systems acquire processed data from the AIMS rather than from the physiologic monitors. To avoid the latency issues discussed previously, it may be advantageous for the CDS to obtain the physiologic data directly from the monitors. Direct communication from the monitors to the CDS will allow the rate of data transmission to be determined by the monitors rather than the AIMS. Furthermore, virtually all monitors can transmit the continuous physiologic waveforms displayed on their screens and not just processed parametric values, such as systolic, diastolic, and mean BP. The CDS could perform processing of the waveforms to yield information not readily available in current monitors or the AIMS. Examples include respiratory variation of the arterial BP or the upstroke slope of the capnogram.

This type information could be quite helpful in CDS rule sets. Other more subtle changes in single physiologic waveforms or combinations of waveforms could be detected by a predictive analytics engine[81] incorporated into the CDS. The waveform analysis would therefore be part of the CDS rather than being dependent on individual monitor manufacturers. In addition to integrating more information from physiologic monitors, the CDS of the future will obtain information from more EMR sources. Information from the preoperative anesthesia assessment and laboratory studies already flow into AIMS and CDS systems. Information from the hospital blood bank, radiology, and cardiology should be closely coupled in the future. The CDS could even obtain information from population, disease, and genetic databases. Management recommendations from the most recent practice guidelines could be made available at the touch of a button.

Predictive decision support would also require more sophisticated processing of real-time data. Robust signal processing methods to efficiently and accurately extract information from physiologic signals would be required. To combine information from multiple sources and to predict adverse outcomes, techniques such as machine learning[82–84] could be used in the future.

An extension of predictive decision support would be potential prescriptive decision support systems. In prescriptive decision support not only are impending adverse clinical events predicted, but also the best treatment option prescribed. Prescriptive analytics combines statistical and computer sciences with analysis of past data and prescribes an optimal course of action.[85] Patient outcomes are predicted for different treatment actions, and the best predicted result is used to recommend the best treatment option.

In addition to predictive and prescriptive decision support, future systems could provide patient-centered decision support. The current trend to standardize care through evidence-based guidelines and protocols is helpful in minimizing provider variations in care. The CDS systems can certainly play an important role in implementing standardized protocols and care guidelines. However, customizing care for an individual patient or surgery within the boundaries of an evidence-based guideline may be the future direction of care.[86,87] Toward this, a CDS system may need to use models of patients' physiology and dynamically integrate patient and surgery characteristics.

CDS systems hold promise in improving patient care during the intraoperative care period. When implementing such systems, consideration should be given to tightly integrate the CDS with AIMS to eliminate the need for data interfaces and to minimize data latency. Ideally, a notification mechanism that is part of AIMS should be used to improve reliability. Notifications should be targeted to the provider who is able to address the issue or take action. The notification message should clearly describe the issue or recommended action and should not obstruct user interactions with AIMS. Care should be taken to minimize the risk of alert fatigue, balancing the need to capture a provider's attention against keeping the CDS notification frequency low. The system should provide an intuitive rules builder module so that decision rules can be constructed easily and saved in a standardized format. There should be a provision to prioritize decision rule, specify notification mechanisms, and compose notification messages. It should be emphasized that a CDS system is simply an electronic tool. Success not only depends on the capabilities of the tool, but also on how the system is used in the context of a clinical setting. Provider acceptance of the decision logic and recommendations by the CDS is important. So also, eliminating operational barriers that prevent providers from acting on the CDS recommendations are equally important.

## DISCLOSURES

**Name:** Bala G. Nair, PhD.
**Contribution:** This author helped structure the manuscript, contribute to writing, and finalize the manuscript.
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**Name:** Eilon Gabel, MD.
**Contribution:** This author helped contribute to writing and finalize the manuscript.
**Conflict of Interest:** None.
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**Contribution:** This author helped contribute to writing and finalize the manuscript.
**Conflict of Interest:** None.
**Name:** Howard A. Schwid, MD.
**Contribution:** This author helped contribute to writing and finalize the manuscript.
**Conflict of Interest:** None.
**Name:** Maxime Cannesson, MD, PhD.
**Contribution:** This author helped contribute to writing and finalize the manuscript.
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