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Innovating Clinical Decision Support for a Multi-Parameter Patient Monitoring System

Co-creating User Requirements Utilizing User Centered Design

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This research used action design research methods, qualitative and quantitative methodologies, user centered design, and the new, Lean-based Fastworks technique to gather voice of customer (VOC) input from an international base of clinicians (n=53) for a new concept in patient monitoring.

This research was conducted during the product research phase at the case company, a global provider of healthcare patient monitoring systems. This research determined the clinical user requirements and application preferences for the innovative Clinical Decision Support (CDS) patient monitoring concept in pan-hospital environments.

CDS was unchartered territory in the case company's patient monitoring business; the needs of the user were unknown. The user requirements were co-created during five intense, iterative collaboration sessions between the researcher and clinicians from professional user groups composed of physicians, nurses, and respiratory therapists.

The research results include the usefulness and utility of the design, visualization preferences, application preferences, clinician group use preferences, monitoring touch points, data and display presentation factors, predictive analytic preferences, clinical practice autonomy factors, additional user needs, and care area use differences. The research presents a practical application of CDS and links this case to potential healthcare and economic value benefits. This research also presents a novel method for ranking user requirements and user preferences.

CDS is seen as the first step in the journey to transform the way that clinical monitoring information is processed and presented to the clinicians. The full results of the research are published internally at the case company.

Keywords	Clinical Decision Support (CDS), Multi-parameter patient monitor, Co-creation, User Requirements (UR), Voice of Customer (VOC), Fastworks, User Centered Design

Contents

ACRONYMS

The following is a list of acronym definitions used in this research.

Acronym	Definition
AI	Artificial intelligence; machine-based human-like intelligence.
ANE	Anesthesia department, the unit in the hospital where surgeries are performed, where the core competence is anesthesia and surgery.
ATD	Advanced Technology Discipline; an iterative engineering process used at General Electric Healthcare during the research phase of potential product design.
CAB F"x"	Clinical Advisory Board Focus (if group ID, x=1; CAB F1 = focus group 1, etc.) Naming convention for five focus groups studied during this research.
CDS	Clinical Decision Support; method of presenting data and information on a patient monitor to support clinicians in decision making.
CIC	Clinical Innovation Council; Company initiative, a network of company internal clinicians promoting innovation in healthcare.
CTG	Cardiotocography; Simultaneous measurement during pregnancy of the maternal contractions and the fetal heart rate. It is a monitor of fetal state.
CTQ	Critical to quality; a Six-Sigma methodology term. Key measurable characteristics of a product as defined by the customer. They align improvement or design efforts with customer requirements. A CTQ is a measureable, quantitative engineering specification based on customer (clinical end-user) input.
EHR	Electronic Health Record; an electronic collection of patient health information over time. EHR may incorporate patient specific data such /current diagnoses and medical history, past pharmacology history, laboratory and radiology reports, clinician annotations, and singularly monitored data (such as blood pressure or pulse).
FDA	Food and Drug Administration, the regulatory authority over medical devices in the USA.
F2F	Face to face, meeting in person versus a virtual meeting.
GE	General Electric Corporation the case company (Healthcare division).
GUI	Graphical User Interface; The patient monitor screen view that the clinical user interacts with and uses to gather information.
ICU	Intensive Care Unit; generic term for a hospital department which cares for persons in need of critical (intensive) care. Can be specialized, for example neonatal, pediatric, cardiac, medical, etc. In these cases, common practice is to put the first letter of the specialty unit in front of the acronym: NICU = neonatal intensive care.
KOL	Key Opinion Leader; a person who is professionally endowed and esteemed by their peers, able to provide deep focus and information related to their field. KOL were interviewed during voice of customer data collection.
MVP	Minimal viable product; strategy in product development for rapid (prototype) testing of product or feature with the goal of obtaining feedback. Used here as input for the Fastworks process.
NDA	Non-disclosure agreement; Legal contract binding the parties to confidentiality.

Acronym	Definition
NPI	New program integration; an iterative engineering process used at General Electric Healthcare during the development-to-market phase of product design.
OCRG	Oxycardiorespirogram; a graphical trend view used in neonatal care to determine root cause of apnea.
OR	Operating Room, also Operating Theatre; anesthesia unit room where surgeries are performed.
PACU	Post anesthesia care unit, the transitional unit after anesthesia unit. From here, patients may transition to the ICU, another unit in the hospital, go to another hospital/ care center, or be discharged home.
PMI	Post Myocardial Infarction; clinical cardiac event which may happen during the post-operative state of the patient.
R&D	Research and Development, cooperative departments in product design having a differing focus. The research department proposes new ideas; the design department will commercialize the products.
SpO_2	Measurement of peripheral oxygen saturation, labelled %.
UCD	User Centered Design; a philosophy of industrial design in which usable products are made so that they are usable by a normal end-user, translating high level technology to an application that can be used in the real-world.
UR	User Requirement; Design term for what the defined end-user of the product needs.
VOC	Voice of Customer; Process of systematically collecting user opinions and needs. User requirements can be determined from VOC.
XML code	Software coding language that has a set of rules for encoding documents so that they are both human and machine-readable.

Thanks for including me and encouraging me to think outside the box with our day to day clinical practice.

- CAB F3 participant 18

1 Introduction

Patient monitoring is at a pivotal point of development; it is time for change. While patient monitoring is a routine event in hospitals and provides the clinical end-users with a vast amount of information, the usability of the monitoring information is questionable. Current problems related to the structuring of information presented during patient monitoring are that the monitors do not show clinical correlation between the data collected from the patient to the actual clinical state of the patient (IOM 2012: 176). The data is presented to the users in a primarily real-time format, and the parameters which are measured are not presented in a correlation state. There is a large amount of biophysical data which is not interconnected in any way. The current solutions require the clinician to search through many data sets and screen views in order to see the clinical picture, to see the cause and effect of treatment, and to potentially identify early warning signs of negative health-related events. These interconnections are not visible or transparent on the patient monitor. The patient monitor screen view shows a limited, one-dimensional, and current view of the patient.

Patient monitoring data needs to be made usable and its interpretation needs to be intuitive. This research was performed as a part of a technology research program at a large, international patient monitoring business with the focus of creating a clinical decision support system for patient monitors. The aim of the technology research program was to provide a novel, flexible and dynamic visualization application to the patient monitor, thereby changing the current practice of patient monitoring.

This research applied user centered design to determine clinical user requirements for the new clinical decision support application platform; the design was co-created with clinical end-users. This research utilized action design research methods. Both qualitative and quantitative methodologies, as well as a new, Lean-based Fastworks technique were utilized to gather input and voice of customer (VOC) feedback from an international base of clinicians. The feedback provided the input for the user requirements. Additionally, a novel method for ranking user requirements and user preferences has been employed.

1.1 Evaluation of business strategy imperatives

General Electric (GE; hereafter, “the company”) is a global multi-conglomerate that strives to continually evolve. The success of the company is something that is dutifully worked on, measured, and improved in a continuous cycle. The company is expansive and works to assure that it is not stagnant and that its performance is not burdened by its mammoth size (Hamel 2007: 37).

Part of the company’s strategy is to have a portfolio that plays to strength. The strengths are based on strategic imperatives. Two strategic imperatives for growth are listed in the company’s 2012 annual report (GE Works 2013: 6): “Superior Technology” and “Enhancing Customer Analytics” (Figure 1) are reviewed in this work. For the company’s healthcare patient monitoring business, Superior Technology has previously entailed providing solid, verified patient measurement parameters for multiparameter monitoring to its clients. Analytics has not previously been a focus of healthcare patient monitoring.

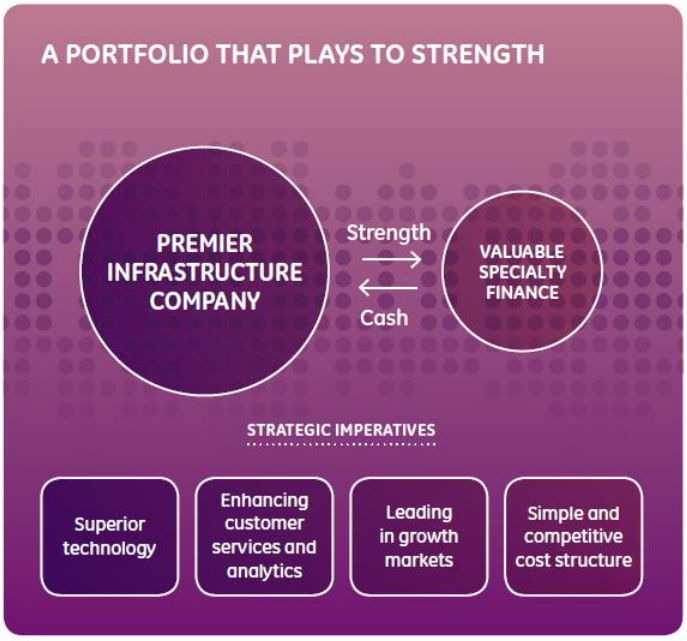


Figure 1: GE’s strategic imperatives (GE Works 2013:6). The company’s Annual Report (2013: 46, 72) states that its Healthcare Patient Monitoring Business provided 18.3 billion USD in profits to the entire profit pot of GE’s approximately 147.4 billion USD 2012 revenue, or roughly 12%.

With healthcare as a science seeking constant improvement in quality and care practice, adding a new parameter to the patient monitoring portfolio may be a factor in

the continual improvement cycle. New parameter measurements would provide the clinicians with more information on their patient's state. New measurement parameters are viewed as potential clinical practice differentiators. As the amount of scientific trials and their subsequent publication are reflectively increasing, the amount of high quality, evidence-based clinical practice differentiators increase. This would make it seem that new changes and improvements to healthcare are continually appearing on the horizon, ready to change healthcare. However, it can take up to seventeen years for this best-practice evidence to be integrated into clinical practice, if at all (Balas, Boren 2000: 65 - 66). Changes and improvements in care practice are introduced in medical literature, but for the most part they are not adapted into clinical practice. According to the long time for best-practice integration, clinician acceptance and rate of adoption of new technologies and treatments places them in Rogers' late adopter/laggard adoption category for innovations (Rogers 2003: 267 - 297). The introduction of new monitoring parameters could be met with the same delayed acceptance as has been seen in other clinical practice initiatives, both related to care methods and pharmacological agent treatment. This time span is too long as a primary source of growth in a business; the turnover is too slow. New monitoring parameter concept additions to healthcare provision should not be introduced.

In light of this, it can be argued that innovation in the patient monitoring medical device industry should rely on short-term growth with internally created enhancements to increase value to the clinical end-users, the customers of the business. Along with "Superior Technology", the company named the "Enhancement of Analytics" as a growth strategy. This could be a faster approach to business growth. Enhancing analytics would be initially equivalent to improving the analytical methods; potential solutions include items such as improving trending and/or providing application packages with parameter trend combinations presented in a context relevant method. The challenge of iterative analytic improvement in a multiparameter monitor was presented to a healthcare research team.

1.2 Current status of patient monitoring and innovation proposal

Harvard Professor Clayton Christensen gave healthcare businesses a clear cue for business opportunities when he advised to "invest less money in high-end, complex technologies and more in technologies that simplify complex problems" (2000: 110). Established businesses or organizations, such as the case company, can use relatively non-complex innovations with low-complexity in order to create growth (Christensen

2004: xv - xvii). Growth from innovation would meet the company's strategic imperative. The solution may be to simplify a complex problem. Hospital based patient monitoring is very complex. Could it be made less complex?

In reviewing the current monitoring practices in the hospital, many observations were made. Hospital clinicians have used complicated, multiparameter patient monitors as an assistive tool for many decades. Patient monitors assist the clinicians in assessing their patients' status and care responses by presenting acquired real-time biophysical signals on the patient monitor screen in the form of curves and numbers. The systems are in themselves complex, and the information they provide is highly specialized. The presentation of information such as vital signs is shown in separate fields, numbers, or waveforms, and not in any form of relationship to one another (IOM 2012: 176). This data presentation style is scattered and singular (Figure 2).

Figure 2: Picture of a typical multi-parameter monitor's screen view during normal patient monitoring in an intensive care unit (ICU). Patient monitor is a GE Datex-Ohmeda brand in actual use. Note: language selected is Finnish.

Although retrospective trend views are supported in most multiparameter patient monitors, their resolution is poor (related to the averaging time) and there are no

interrelationships between the views and a health state (Figure 3). In addition, these trend views are programmed to be found behind a labyrinth of menu choices.

Figure 3: A patient monitor screen view with one trending page of eight trends shown in graphic format. The retrospective view is minus two hours. Simultaneously, an ECG tracing is taking place in real time (top) and real time measurements are shown in the window view on the right hand screen. (Simulated signals)

Using the patient monitor as an example, the research team made a proposal to decrease patient monitoring complexity by changing the presentation format of the patient monitor's graphical user interface. For instance, the grouping of hemodynamic parameters could give a better inter-relationship understanding of the clinical picture, or could even serve to predict or diagnose an event. This would be, in its simplest essence, turning curves and numbers into meaningful clinical data which can be used to enhance the knowledge of the patient's state and thus further enhance patient care. Clinical Decision Support (CDS) was initially defined by the team as a method to provide intelligently filtered, prioritized and actionable information, visualized in a clinically relevant manner. This is something that is not currently done with patient monitors.

2 Theoretical framework

2.1 Research focus

The questions posed for this research are the following:

- What are the clinical end-users' requirements related to the clinical decision support framework in a multi-parameter patient monitor?
- What are the clinical end-users' preferences related to clinical decision support applications?

2.2 Research design

This research utilizes action design research methods to develop practical and relevant solutions to the research questions. Action design research is grounded in the assumption that the designed outputs are "shaped by the organizational context during development and use. The method conceptualizes the research process as containing the inseparable and inherently interwoven activities of building the (product), intervening in the organization, and evaluating it concurrently" (Sein, Henfridsson, Purao, Rossi, and Lindgren 2011: 37).

The engineering team believed the novel CDS solution would bring a change to the practice of data utilization in multi-parameter patient monitoring. It had been noted that improvements to existing products are often over-engineered. There have been many cases of clinician uncertainty as to the provided technical solutions, as product architecture was not rooted in the clinical mind-set (Christiansen 2000: 104).

By applying action design research methods, the CDS concept could be mutually framed from a user perspective. Developmental emphasis would be placed on creating relevant and clinically usable solutions (Sein et al 2011: 40 – 45; Dresch, Lacerda, and Valle Antunes 2014: 77 – 97; Cole, Purao, Rossi, and Sein 2005). By systematically collecting Voice of the Customer (VOC) data, user (=customer) opinions and needs are recognized and co-creation of the output can occur. Co-creation in a reflective, cyclical VOC process would be an ideal method of CDS development, as solutions would be made in tandem with practitioners who have clinical workflow domain expertise. Co-creation of product concept should contribute positively to the design, utility, and working principles of the CDS (Sein et al 2011: 41- 45; Dresch et al 2014: 60). Through VOC abstraction and analysis, user requirements and preferences can be determined.

3 CDS in literature

As there was very little researcher knowledge about CDS, the first step of the research was to review the CDS concept via current literature. Literature for review was deemed to be current if it was under ten years since publication. Literature was considered topical if it was related to CDS, quality, healthcare informatics, and innovation. Materials over ten years old, including international standards and/or regulations governing the medical device industry, were allowed for the research for use in other sections as reference.

3.1 Levels of CDS

The literature divided CDS into a three-level concept, with each level building on and supporting one another. For patient monitoring, the three levels of CDS are described and detailed in Figure 4. The first level of CDS, Level I, is essentially equivalent to the current patient monitoring solution. Level II would build on a Level I platform and group data sets together in new ways to deepen the clinician's view of the clinical state of the monitored patient. In the highest level, Level III, there is actual clinical assistance provided to the clinicians in some form of an integrated industrial internet (O'Reilley, Steele, Loukides, and Hill 2012; Bruner 2013: 1 - 13, 27 - 31, 34 - 35) and other electronic patient data systems, for example electronic health records (McKibbon in Kudyba 2010: 129 - 141). Decision trees are rule-based, adapt the knowledge from many sources of input, and solutions may even be so advanced that they drive the treatment (for example, perform closed-loop anesthesia).

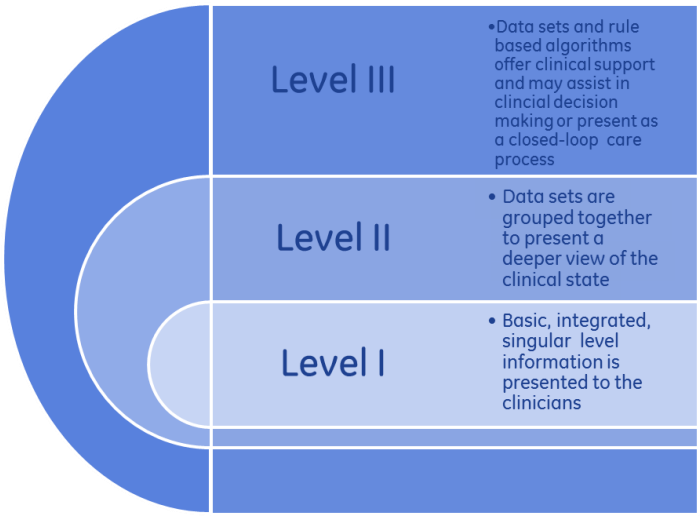


Figure 4: CDS systems represented in three levels of use and information inclusion, each a progressive extension of the previous level (by researcher).

The three levels of CDS are further broken down in Chart 1. The CDS solution proposed by the company during this engineering program is Level II. The literature supported the creation and use of Level II CDS methods in patient monitoring. More advanced analytics in the true sense of analytics would be Level III CDS and could be a natural progression from Level II. It should be considered that a new feature of care reminders be added to the CDS solution, as they could improve the healthcare process. Alarms and alerts are a regulatory requirement for patient monitors and are present in the company's current monitor portfolio.

CDS level	Description	Detail	Example
I	Multiparameter monitoring of a patient	1. Brings patient biophysical signals to the clinician in real time. 2. Basic alarms are presented 3. Parametric use of information presented	1. Data presented on screen as numeric and/or waveform. 2. Alarms presented per IEC 60601-1-8 3. Basic care suggestions related to monitoring (e.g. "Inject Now" for cardiac output monitoring calibration) are presented on the screen during the clinician-performed calibration procedure.
II	The bringing together and integration of two or more data sets from the patient monitor and then integrated on the screen to present a parameter presentation using clinically relevant, real time data and at least dual parameter trending to assist the clinician in assessing the state of the patient and individual response to care.	All Level I and: 1. Enables effective grouping and translation of patient monitor output to the clinicians for increased awareness and knowledge related to the patient state. 2. In addition to basic alarms and care suggestions, reminders/ inter-correlation/ presentation/ color-coding/ messages of selected parameter groups adds clinical decision support by providing parametric relevance for the clinician. Trending is high resolution. Potential for default and customized views.	1. Different data views: bar graphs, radar views, color coding, optimal therapy levels, markers, etc. 2. Care packages, either pre-configured or self-configurable, built on a template or self-coded. 3. Context relevant-trending
III	The bringing together and integration of two or more data sets from separate sources, either retrieved from various hospital information systems or	All in Level I and II and: 1. the integration of a patient Electronic Health Record (EHR) and an Artificial Intelligence (AI) system which in turn: a. diagnoses,	1. Automated diagnosing or care suggestions based on multiple input sources 2. Care reminders and/or attention items such as patient allergies during

CDS level	Description	Detail	Example
	entered by a user (in this case, a clinician). The patient specific information is then integrated further into a database containing clinical data rules which assist the clinician in diagnosing and even treating the patient.	b. warns of impeding changes c. and suggests interventions in clinical de-cision making.	planned pharmaceutical intervention (ex: allergic to Penicillin) 3. Fully to clinician approved closed-loop care

Chart 1: Three levels of CDS described, detailed, and examples provided. Chart by researcher incorporating from Tappan (2009: 223 – 224), McKibbon (in Kudyba 129 – 141), Berwick and Bisognano (in Juran 2000: section 32.8 - 32.9 and figure 32.1), Teich, Ash, Campbell, Bates (2008: 388) and Coiera (http: //www.openclinical.org/aisinpracticeDSS.html).

One large systematic review of 148 publications through 2011 showed that Level III CDS systems could improve the care process in many healthcare settings by providing reminders, alarms, and alerts. This review found that there was little outcome evidence for clinical, economical, efficiency or workload with a Level III CDS system. This review also showed that use and implementation outcomes for a purchased or self-made Level III CDS implementation were moderate to poor (Bright, Wong, Dhurjati, Bristow, Bastian, Coeytaux, Samsa, Hasselblad, Williams, Musty, Wing, Kendrick, Sanders, Lobach 2012: 29 - 43).

3.2 Need for CDS application

The patient monitor's data presentation needs improvement and modernization. The creation of a more intuitive, health-state supportive display would ease the interpretation of the vast amount of data and thus provide monitoring data in a usable form that the clinical user can interpret and then act on in a clinically accordingly way (Sittig, Wright, Osheroff, Middleton, Teich, Ash, Campbell, and Bates 2008: 388).

Design safety is a factor which should be inherent in medical device design. In spite of this, the IOM feels that "designing information presentation to minimize safety risks with minimum effort is still an unsolved problem" (IOM 2012: 172). If the clinician does not recognize the subtle changes during the continual monitoring procedure, patient safety could be at risk (Tappan, Daniels, Slavin, Lim, Brandt, and Ansermino 2009: 223 – 224). In Figure 5, the clinical workflow during the critical period from an early, unnoted

departure from a desired physiological state to the potential for serious adverse events is described. The time period for rescue interventions is decreased, as the departure from the normal physiological state is not noted. This unrecognized departure and the decreased time for interventions may then lead to serious adverse events, causing a missed opportunity for the clinician to react to the patient's subtle clinical changes.

Figure 5: The clinical flow of a patient receiving long-term monitoring and the risk for non-recognition of changes in physiological state patterns. This clinical pathway flow could apply to an ICU patient, for example. Figure by the researcher (adapting Tappan et al 2009: 223 – 224).

Using CDS, the potential for early intervention could prevent the occurrence of serious adverse events by identifying and making evident the subtle changes and patterns in health state. Clinical knowledge and assessment skills must be paired with any technology, including the CDS; it is not a replacement for clinical practice.

Many studies include the importance of Electronic Health Record (EHR) incorporation into the CDS. There have been calls to unify the various electronic patient data, but these calls are largely focusing on combining EHRs or computer reminders for care protocol interventions such as follow-up visit scheduling in out-patient clinics (McKibbon in Kudyba 132 - 133).

3.3 Theoretical CDS applications

Patient cases can be fairly simple and straightforward to multifaceted and complex. "Scientific progress moves disorders that used to be dealt with in a problem-solving mode toward a pattern-recognition mode and those that had to be addressed through pattern recognition toward a rule-based regime" (Christensen 2000: 109). Some clinical cases can be diagnosed and treated using a rule-based strategy; the clinician is able to recognize a pattern in the presentation and is then able to act on it using best practice methods (Christiansen 2000: 108 - 110).

This best practice, rule-based clinical assessment method has been used, for example, in the diagnosing of bronchitis versus pneumonia (Berwick and Bisognano, in Juran 2000: section 32.8 - 32.9). Using a simplified inspection model, a differential diagnosis for bronchitis can be made. The iterative steps of planning medical or nursing intervention are shown in Figure 6, which relies on pattern recognition based on experience.

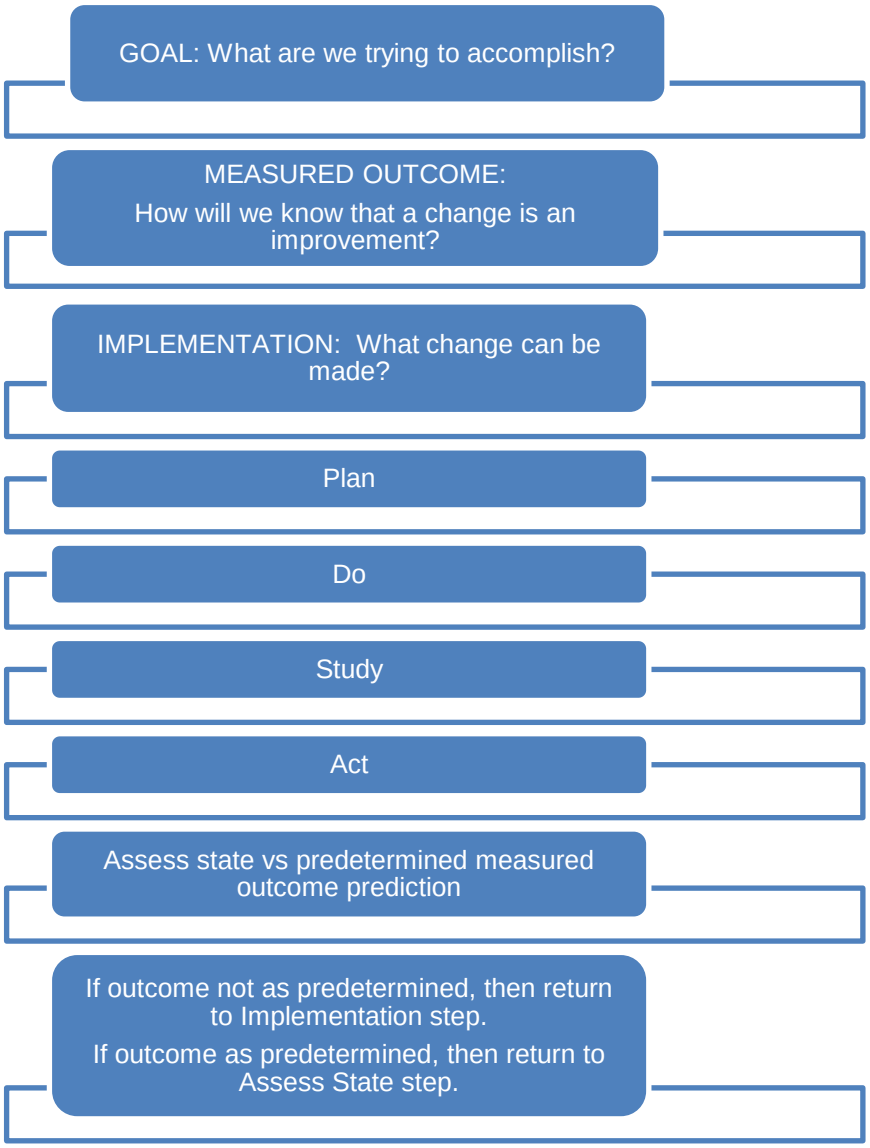


Figure 6: Iterative steps in improving healthcare delivery and treatment, by the researcher (adapted from Langely et al 1996 in Berwick and Bisognano 2000: Sections 32.7 – 32.11). This process mirrors action design research, and also the Fastworks process (section 4.5).

With a combination of protocol and workflow driven CDS, researchers have also been able to create adaptable models for the treatment of sepsis. Sepsis is a systematic inflammatory response to infection, carries a 20 – 30% mortality rate, and there are an

estimated 19M cases a year globally with all patient groups at risk. Sepsis parameters which can be measured on a multiparameter patient monitor are core temperature, heart rate, respiration rate, arterial hypotension, systemic venous oxygenation, cardiac index, and arterial oxygenation (Adhikari, Fowler, Bhagwanjee, Rubenfeld 2010: 1339 - 1346; Angus, van der Poll 2013: 840 – 851).

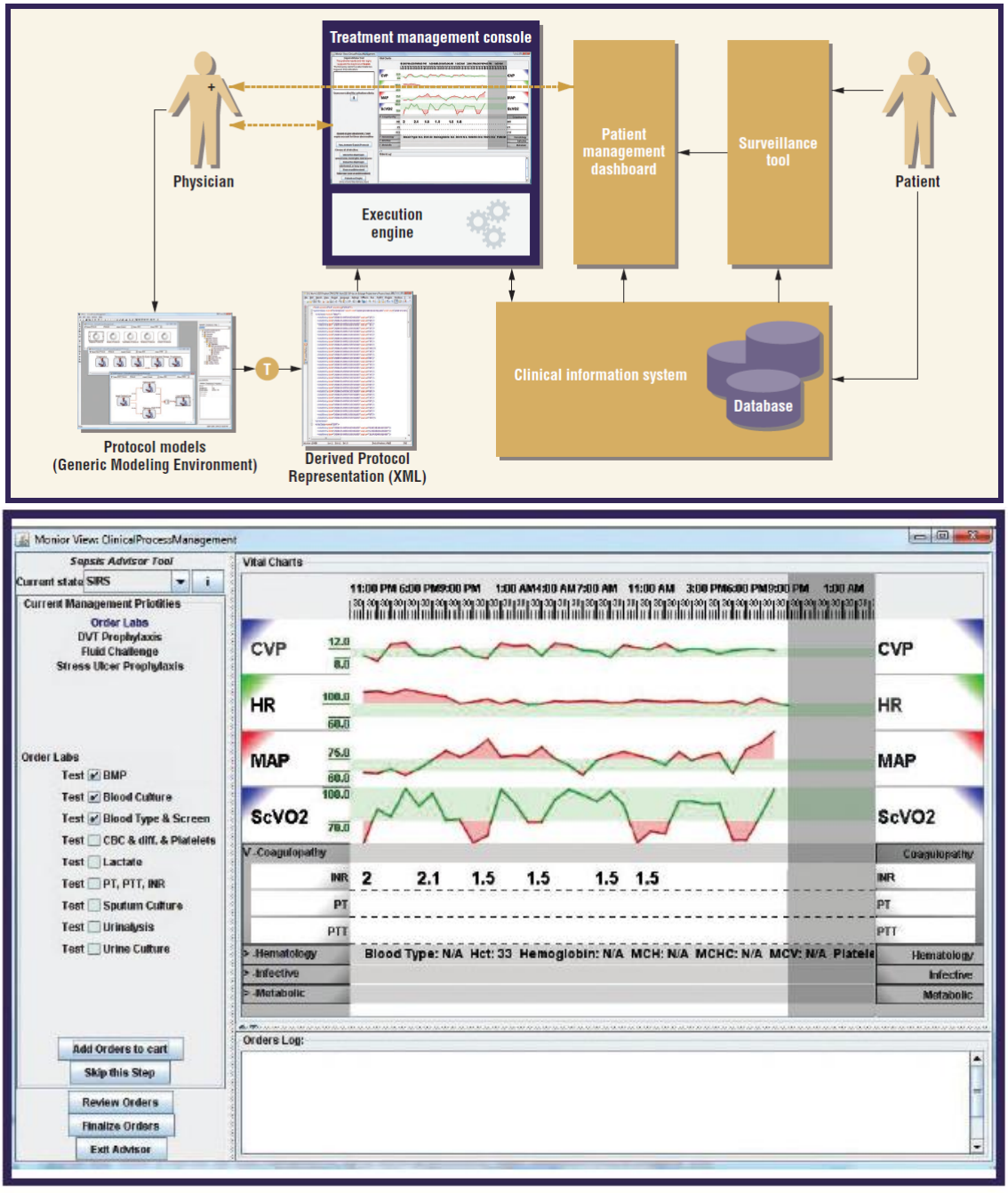


Figure 7: Modelling of a sepsis surveillance CDS (Mathe et al 2009: 55-56).

Figure 7 demonstrates the derived protocol's realization and the modelling method behind the sepsis protocol. In the figure's top picture, the pre-utilization physician-

driven protocol creation for sepsis is shown (Mathe, Ledeczi, Nadas, Sztipanovits, Martin, Weavind, Miller, Miller, Maron 2009: 54 - 61). Using this model, user-defined input can be customized by the treating clinician for the individual case by manipulating the derived protocol representation data (XML code). The patient management dashboard (lower picture) includes information from the patient monitor (surveillance unit) and the named sepsis protocol guided care plan (patient management dashboard) and is the displayed in the upper picture of Figure 7 as the treatment management console. Although this tool was not validated at time of publication, the premise of two-fold interaction could support a working Level II CDS.

CDS may also have implications on professional role. With CDS type applications, there will be a shift in the focus of knowledge; where nurses were once low on the healthcare provider pyramid, CDS technology can assist them in rising and being dynamic changers of the medical profession (Christansen 2004: 185 – 191), as CDS would give a deeper understanding of monitoring in relation to patient care. The technology may have an effect on clinical practice.

3.4 Actualized Level II CDS applications

In the neonatal intensive care unit (NICU), clinicians can use a trend view graphical user interface, a basic Level II CDS, called the oxycardiorespirogram (OCRG). With the OCRG, neonatal clinicians have long been able to detect and diagnose three forms of apnea of prematurity: obstructive, central, and mixed (Catley, Smith, McGregor, James, and Eklund 2011:18 - 21; Zhao, Gonzalez, and Mu 2011: 1097 - 1105). By observing and interpreting the trending of three simultaneously acquired and high-resolution trended parameters always presented in the same hierarchical order from top to bottom (heart rate, SpO_2, and respiratory rate), the clinicians are able to determine the type of apnea based on the relationship among the three parameters (Figure 8). The patient monitor does not give the diagnosis nor suggest a care protocol; this is for the clinician to determine. However, the view allows for the determination, association, and exclusion of health events surrounding the apnea events and assists the clinician in determining the care pathway. OCRG as a visualization method is an example of CDS being used as a continuum of care.

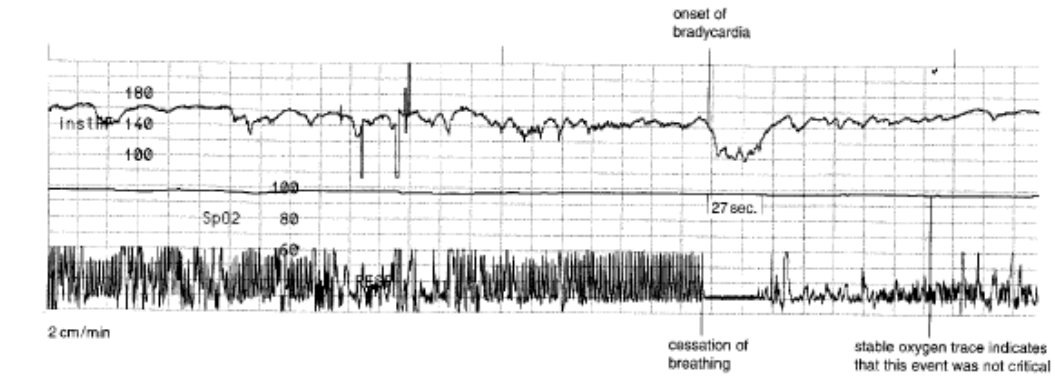


Figure 8: An example of neonatal central apnea is represented on this CDS style OCRG tracing. (Agilent 2001: 4)

In the hospital labor and delivery setting, before the infant is born, the reaction of the unborn baby's heart rate to the contractions or other external factors is monitored with a cardiotocography (CTG) machine. The use of the CTG is standard of care during intrapartum fetal monitoring. The CTG is a monitor (either invasive or non-invasive) which used during labor measures factors from both the mother and the unborn baby. The CTG registers the heart rate of the infant via a signal acquired from a scalp electrode and the contractile state of the uterus from a belt applied around the mother's lower abdomen. The CTG records both the strength and duration of uterine contractions along with the unborn baby's reaction to the uterine contractions. The two plots are viewed as both a real time event and a long term, historical trend (Kramme, Hoffmann, and Pozos 2011: 1019 – 1029). By viewing and interpreting the trended data, the clinician is able to assess the baby's antenatal state and can even identify factors such as fetal distress and umbilical cord compression.

The CTG is a unique form of CDS. It is the monitored symbiosis of two beings – one born and the other unborn. It is focusing on the fetus' reaction to its external environment (mother's contracting uterus) and to its own immediate environment (umbilical cord compression, other distress). This changing state is monitored and diagnoses are made based on the CTG CDS presentation.

When viewed as clinical state related themes, attribute categorization (=selected parameter combinations) could support clinicians in cause/effect trend identification

and the possibility to predict upcoming patient events based on short-term historical trends. CDS, in turn, would increase value to the patient monitor by improving the patient monitor's usage, enhancing signals and weaving together clinically significant combinations, and adding a new level of depth to the practice of monitoring for the clinical end-user (Sittig et al 2008: 388). The use of the CTG and OCRG intelligently integrated multi-parameter displays could be bridged to, for example, potential diagnostic pan-hospital events such as sepsis or cardiac events.

3.5 Human factor risks during patient monitoring

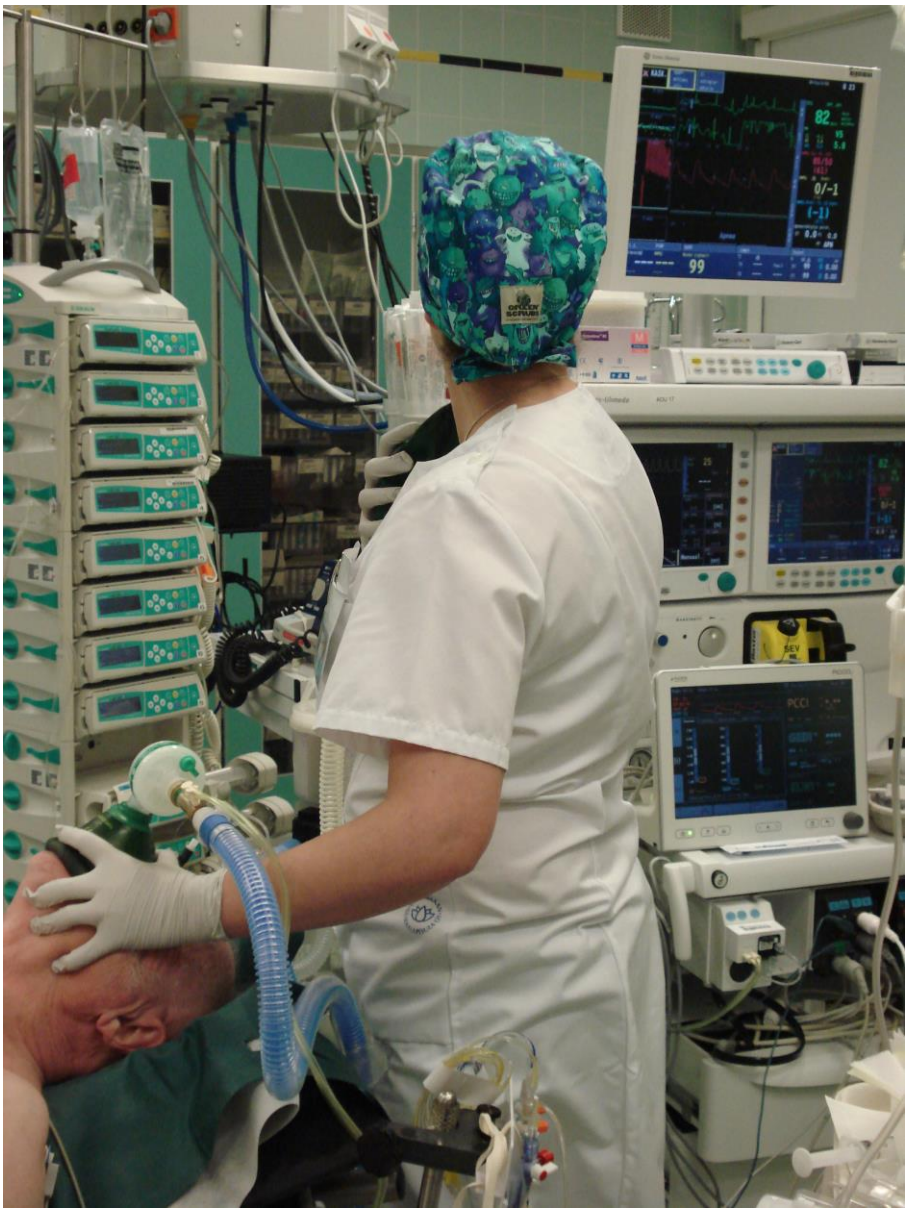
Clinicians in the ICU and anesthesia departments are met with information overload on a daily basis. These clinicians are treating and caring for many patients simultaneously. Each clinical case is different in its complexity and depth. It has been estimated that clinicians have to keep track of approximately 11,000 diseases and conditions, most of which share similar clinical presentations (McKibbon in Kudyba 2010: 133).

As clinical situations and unit needs vary, the multi-parameter monitoring display setting should include the ability to change or personalize the monitoring system configurations (Bloundt, Ebling, Eklund, James, McGregor, Percival, Smith, and Sow 2010: 117). While unique, clinician-customization of the patient monitor data sets would be ideal, this is not practical on a general monitoring level, as there are many and possibly simultaneous users. Preference-changed or individually customized screen views at the general viewing level presents challenges. Furthermore, if each clinician interaction with the monitor would be personalized in terms of screen view, there may be negative effects and potential risks related to multi-user continuity, such as:

- lack of clinical work-flow customization,
- difficulty of analysis,
- prevention of the creation of comprehensive, usable solutions (IOM 2102: 170 - 171).

Additionally, researchers stress that the data deemed to be critical should be present in order for the system to perform (Bloundt et al 2010: 117). Using a small sample of ICU nurses, Doig, Drews, and Keefe found that for nurses, monitor trending should be integrated to show patient response to provided care and that these trends should be easily accessible. Complex hemodynamic monitoring was performed by the nurses, yet there was underutilization of available data provided by the monitor. The main

reason stated for data underutilization was indexed values were hard to find, therefore they were not included in the patient assessment (2011: 706 - 712).



Picture 1: The daily workplace of a higher level hospital anesthesiologist includes many monitors and machines. The picture is taken during the induction phase of anesthesia and contains multiple infusion pumps, monitor screen views, and anesthesia delivery systems. Picture: company files.

Many clinicians utilize care plans and preventative checklists, which include multiple recommended care practices, adding many interventions and actions. However, these checklists have not been collated and integrated into a care plan or daily workflow to reliably ensure delivery of the practices. (Pronovost 2013: E2; Drews 2013: 112 - 118). The addition of time pressures and potential knowledge and skill deficit issues all influence the clinicians' work (McKibbon in Kudyba 2010:133 - 138).

Likewise, the hospital presents potential opportunist health risks for the patient which are not related to the hospitalization root cause. These opportunist health risks include such problems as hospital acquired nosocomial infections, reactions to pharmaceuticals, or sub-optimal ventilator treatment leading to respiratory compromise. For example, the prescribing, dispensing, and administering of pharmaceuticals is a risk for all ages of patient (McKibbon in Kudyba 2010: 137). There is no current linkage to administered medicine and its effect on the vital signs displayed on the patient monitor; this cause and effect dichotomy between physiology and interventional pharmacology must be observed and assessed as a separate process.

Frequent publishers focusing on clinician-based errors, anesthesiologists Marjorie Podraza Stiegler and Sara Goldhaber-Fiebert (2013: 11) describe cognitive errors and anchoring in the clinical setting. Anchoring is described as a problem state during which clinician attention and focus is concentrated, for example, on a presented clinical state such as hypovolemia. The anchored focus on hypovolemia has the potential to distract from a more pertinent state of hypotension. Anchoring can be used as an argument against clinician CDS customization.

Change blindness is another phenomenon during physiological monitoring. Change blindness is the result of the clinician's attention being diverted during the sustained monitoring task, thus causing the inability to note changes in the physiological state (Tappan et al 2009: 224 - 225). These changes can cause missed or delayed patient care occurrences. The risks of anchoring and change blindness should be considered as usability risks during CDS usage, in that the clinician may focus on a certain aspect of CDS monitoring, while providing less attention to other clinical happenings (Carter in Berner (ed.) 2007: 64).

Alarm overload also stresses the clinicians. It has been estimated that up to 99% of alarm signals are either false alarms or do not require any type of clinical intervention, as there is a variety of non-patient root causes for these false alarms (The Joint Commission 2013: 1 - 2). Alarms are so frequent and the propensity for false alarms is so high that indifferentiable alarms disrupt workflow, lead to clinician mistrust of alarms, and are a factor in clinicians disabling the alarms altogether (Korniewicz, Clark, and David 2008: 36 - 41). One report states that NICU staff process over 4 million clinical alarms a year, making one alarm for every two to three minute time period per

nurse (Vergales, Paget-Brown, Hoshik, Guin, Smoot, Rusin, Clark, Delos, Fairchild, Lake, Moorman, and Kattwinkel 2014: 157 - 162). The group also noted that during a two year and two week study of 5275 apnea recorded by the study group's automated algorithm for apnea detection, only 26% of the apnea events were actually recorded by nurses within one hour post-apnea event. Concurrently, the monitor alarms did not sound in 26% of the apnea events, so there were missed events.

3.6 Strategic feasibility of the CDS concept

The three levels of CDS were analysed and defined in terms of data sets and their integration into a patient monitoring system (Chart 2). From a business strategy perspective, this concept is supported and provides an iterative growth model for the concept.

Redman's Strategy Step	**Potential with CDS**	**Affected CDS level**		
		I (current)	**II**	**III**
Provide new content	CDS presents legacy content in a new packaging system – bringing together bio-physiologically linked monitoring parameters per specific health state. Data is targeted per patient type.	Legacy content only (available)	Improved trending of patient health state	Assistive healthcare algorithms
Repackage	Change filtering of signals. Combine many parameters into one screen view. Ability to customize or configure data – even to own mobile device. Access CDS remotely.	NA, legacy design	First step for CDS engineering program: presentation	Potential future steps, including industrial internet and informatics.
Informationalize	Make data useful Let clinician configure own data sets/views	Monitor is configurable for major setting	New CDS configurability, including external devices	Assistive algorithms

Redman's Strategy Step	Potential with CDS	Affected CDS level		
		I (current)	II	III
Unbundle	Allow for legacy screen views, as well – not just CDS	Basic screen views	CDS views, configurability; real-time maintained per clinician need	CDS views, configurability, interfacing to other systems
Exploit asymmetries	Alarms, issue identifiers, and in more advanced levels – care suggestions	Alarms, no care suggestions other than generic cautions, warning (e.g. "leads off" for ECG or "Inject now" for Cardiac Output)	Issue identifiers when changes start and are identified pre-alarm status	Assistive algorithms and care suggestions
Provide identifiers	Create care-specific views, for example sepsis view, OCRG view, cardiac views, Create distinguishable views for the clinician	Split screen views available	Care package applications which are also configurable by the clinicians.	Level II views and integration of industrial internet/big data analytics, care reminders and suggestions, integration to other electronic data.
Infomediate	Make the design usable and intuitive to use (requires usability studies)	N/A, Legacy design	Current program: design with clinicians for user preferences (requires usability studies)	Potential future program. (requires usability studies)
Mine data and conduct analytics	Trend views, customized, bring more "hidden features" to the surface	Trend views unsatisfactory for data analysis	Improved trend view, hidden signals process improvement. No analytics. Templates for healthcare event identification.	Potential for analytics and predictivity/closed-loop care.

Chart 2: Researcher analysis of CDS levels by expanding on Redman's (2008: 34) strategy steps of utilizing data assets (left-hand column) to researcher assessed CDS potential and correspondence to CDS level I, II, or III. In this case, data acquired by the bedside multiparameter monitor is defined as the data.

The concept is feasible from a strategic perspective. The current monitoring platform situation lies primarily in Level I. Level II is the next strategic step for the company to pursue and appears feasible.

3.7 Literature review summary

The literature review supported the creation and use of a CDS system. There was little to no literature with a sole focus on CDS as planned by the research program. However, concepts were extracted from the works to support and advance the development of CDS as defined by the technology research program.

Using CDS, monitoring information could be tailored and presented in a more patient-centric way, benefiting both the clinician and the patient (IOM 2001:164). CDS would provide some form of analytics for the clinician via the patient monitor. CDS can be defined as a trend visualization tool. It was envisioned that common, known health status associations (“respiratory status”) or adverse health events (“cardiac failure”) could be used in the presentation and systematization of the displayed monitoring information. Indicators could include clinical alerts and messages from the patient monitor. Using this example, physiological indicators of an impending cardiac state could be pooled together and presented in a common view, thus bringing the puzzle pieces of patient monitoring together.

4 CDS technology program

The following sections are related to the engineering research program for CDS. The program model, the researcher's role, the background to user requirements, and the user centered design approach are included in these sections.

4.1 Technology program model

The CDS concept was the focus of an advanced technology research development (ATD) program at the company. The CDS ATD was a precursor to a New Program Integration program (NPI). The NPI engineering development programs bring proven product concepts to market (commercialization). This division means the CDS ATD would not produce a finished product for commercial purposes but will provide a technology platform and other deliverables for potential integration into NPI programs which would eventually be commercialized (Figure 9). The goal in a technology program is to prove the technology concept and to retire risk.

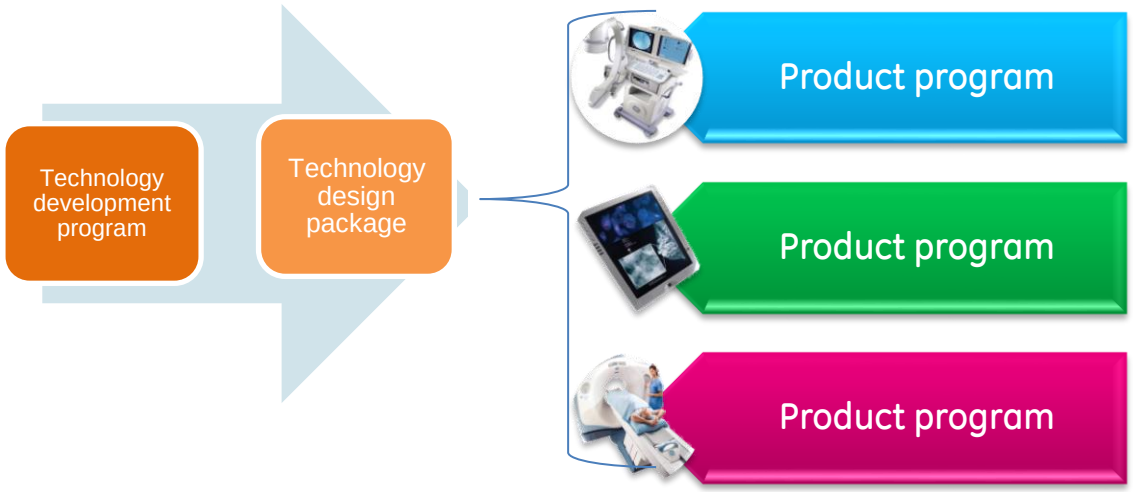


Figure 9: Model of a technology development project and its relationship to product programs. A design package is produced during the technology development program. It consists of technology and documentation that can be used in one or more product programs as a core technology. (Picture by researcher)

This type of non-commercial, not-for-market product development is common in the medical device industry. Medical device regulatory bodies allow for research program activity such as CDS. The regulatory body for medical devices in the United States, the

FDA, states that a medical device company may perform research activities in order to ascertain basic functions or characteristics for a new product. These activities need to be controlled, however, and need to fall under the Quality System (1997: 14 – 15). The CDS technology research program was executed as a part of a formal, iterative, quality controlled process (Figure 10).

The Technology Milestone process provides rigor in the operation of ATD projects; it aids in monitoring project progress and determining when the project is ready to move from the research phase to NPI product phase. Adherence to the T-milestones is to ensure:

- ATD projects are aligned with business needs
- Technical and clinical risks are retired to an acceptable level
- Requirements are effectively captured up front.

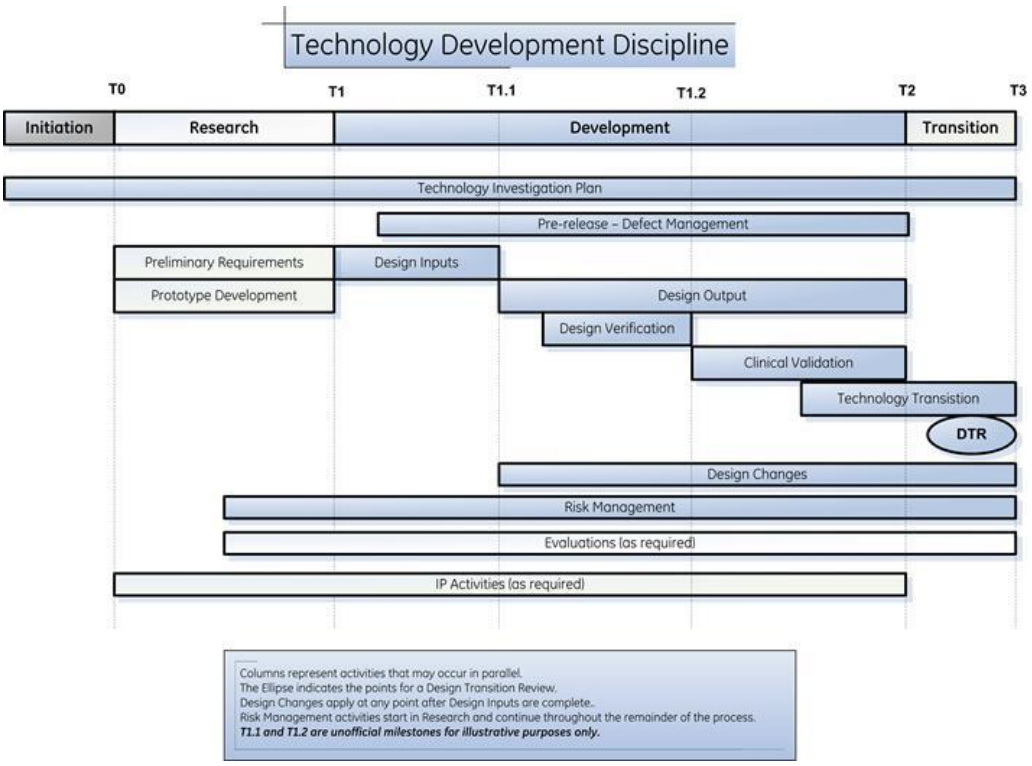


Figure 10: A diagram of the phase review iterative steps and developmental milestones for a technology development discipline program, which was utilized as a framework for this engineering program. The T"X" are milestone markers. To progress to the next level of design, the T review milestones must pass. T0 for initiation finalization was held in January 2014 and passed. The figure is from a company internal process control guideline.

Technology Milestones are iterative and are summarized as follows:

- T0 – Technology Project Defined
- T1 – Technology Scoping / Feasibility Complete
- T2 – Technology Prototype Complete
- TE – Ready for External Evaluations
- T3 – Technology Transition Complete

4.2 Researcher's role in the program

The CDS ATD was an international collaboration; members were located in Finland and the USA. The team was cross-functional and the researcher was a member of this team. The program's operating mechanism was centered on weekly web meetings and simultaneous conference calls led by a program technology manager.

The researcher's role in the program is that of master's thesis student. The task focuses were on these:

- identification of user requirements,
    - including but not limited to interviewing users, writing surveys for the users, participating in VOC sessions, analysing input from the VOC sessions
- performing a literature search for theory and (potential) confirmation of the CDS concept, and
- regulatory aspects of CDS, such as:
    - tracking evolving regulatory trends
    - providing clinical and engineering input to a global group of volunteer regulators (International Medical Device Regulators Forum) tasked with creating regulatory guidance for the medical device industry related to CDS.

4.3 User Requirements as a part of Design Controls

Although technology leadership is crucial in high-tech companies, the collection of user requirements is also critical and vital in creating a product that is needed. The determination of user requirements is one of the formal steps in the development of medical devices and applications, falling under the formal process of product development called Design Controls. Design Controls is a mandatory quality process and is a regulated part of the medical device industry. For a product to be marketed in the USA, the FDA has to provide regulatory clearance. The FDA regulates the medical device industry in the USA and their guidance (FDA 1997: Section C/ Design Input)

provided the definition and scope of user requirements for the purposes of this research.

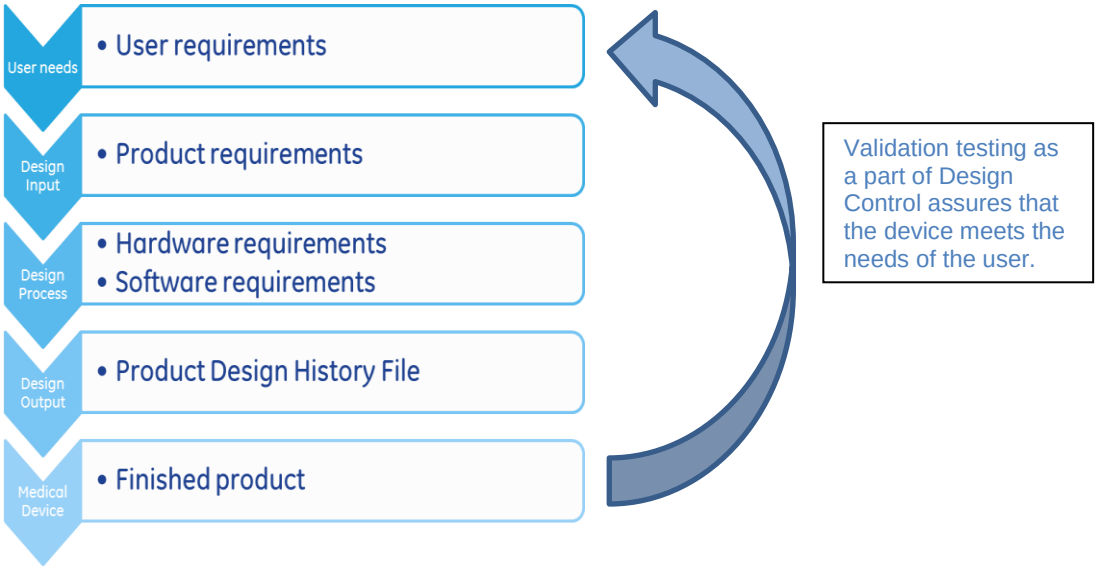


Figure 11: A researcher modified version of the FDA's (1997: 3) Design Control figure representing a waterfall approach to medical device design, emphasizing user requirements as the first and last step (validation) of product design.

The role of the developing team in user input is important, as they are the ones who take the words of the user and put them into engineering terminology, creating something that must in turn be validated by the end-user. The user requirements should specify what the user needs while avoiding specific design solutions (FDA 1997: 14 -15). User requirements are the starting point in the product development process, trickle down to all other phases of product development, and are validated in the end of the process (Figure 11). User requirements are more formal than concept documents (FDA 1997: 14), even during research phases. Documented user requirements fall under the company's quality system. There is a dedicated, internal design control process at the company for user requirements. Initial user requirements for CDS should be written per this process.

4.4 User Centered Design

The basis of the research is to apply the process of user centered design (UCD) into the proposed application of CDS. The process of UCD is illustrated in Figure 12. The

UCD approach is often utilized as it is seen to generate the most efficient and usable products (Demir, Karakaya, and Tosun 2012: 17).

The first step in the UCD process is to identify the end-users and the users' characteristics (Demir et al 2012: 15). User characteristics are the identification of user demographical data. This may include items such as gender, profession, professional care area, education, experience, expertise, etc. The users of CDS are defined as clinicians in the hospital ICU or anesthesia department setting, including the post-anesthesia care unit (PACU).

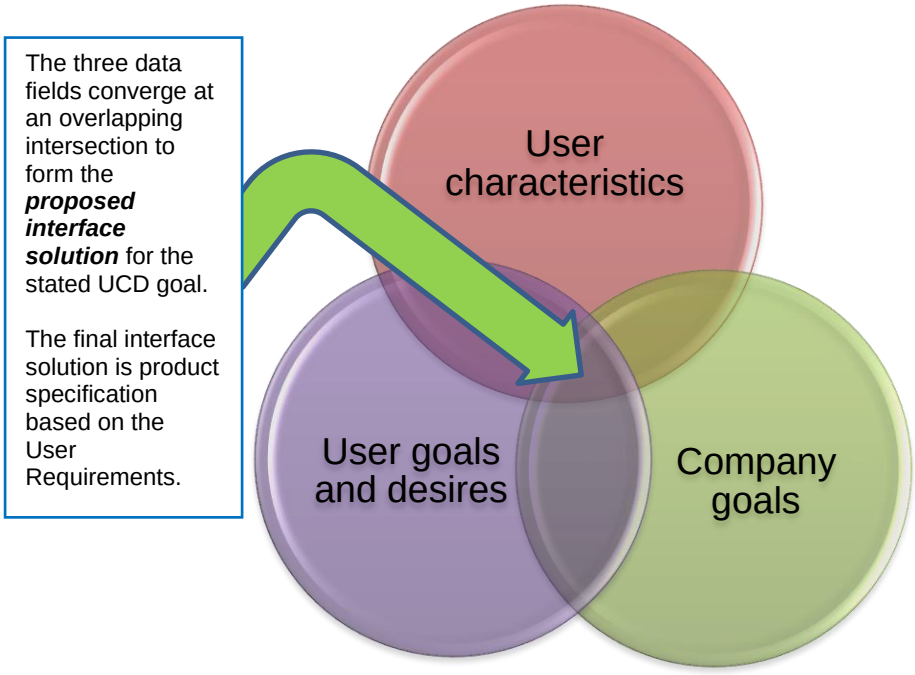


Figure 12: The relationship of data for the proposed interface solution in the UCD process is illustrated in the figure. Adapted from Demir et. al. (2012: 15) by the researcher.

The company goals are equivocated to the engineering program goals. The goal of the technology program is to create an interface solution proposal for the patient. The output of this program will be realized and actuated into a product by a catcher NPI program.

The user goals and desires are the statements potential users outline as the ideal use of the solution. These goals and desires are solicited from potential users. The user goals and desires related to a CDS solution will be named in this work. This means

that the first three of Demir's five steps of user-centered design would be realized for this research (2012: 14-17).

4.5 Fastworks

The engineering team would use the Lean-based Fastworks process which mirrors action design research. All members of the team were trained and coached by a company-based Fastworks trainer. Fastworks uses a build-measure-learn feedback loop and its processes are defined in Figure 13.

Figure 13: The Fastworks Process (from the company's intranet Fastworks site).

The researcher analyzed the Fastworks process (Figure 13) and compared it to action design research and found that the process and method mirror one another. The

researcher proposed this similarity to the research team. It was deemed that Fastworks would be a good, complementary tool for the research. Reporting methods for the program would also incorporate Fastworks concept terms such as “pivot or persevere”. When a program “pivots”, it re-evaluates based on reflection and potentially changes something. “Persevere” points are indicators to continue with the plan based on the output of the reflective process. This is the first time the program members would use Fastworks.

4.5.1 Fastworks Leap of Faith Assumptions

The Fastworks process starts with assumptions the team has related to the concept proposal. The Fastworks “Leap of Faith Assumptions” when starting the user centric research were these:

1. CDS would be accepted as a concept by the users,
2. Professional groups (physicians/nurses) would use the CDS in the same way, and
3. CDS potential solution would include solution-specific concepts, such as:
    a. provision of building blocks
        i. the user has the ability to "tune" the application to suit clinical needs
    b. build-it-yourself application
        i. the user has the ability to make own templates to suit clinical needs

5 Research process

The following sections are related the research process. The methodology and research plans are discussed in more detail in this section's subsections.

This research was started with a literature review. The literature supported the need for a CDS solution. This literature review process continued throughout the research. The research questions grew from the literature and from the engineering program. The research questions helped in forming the research strategy, including data collection methods and timing. The analysis of the data also drew on literature for validation in some areas. The conclusions were garnered from the data and the entire research process.

5.1 Methodology

The methodology of this study was action design research. Action design research was used to determine the user needs and requirements, and to fan out what are not requirements to the CDS solution based on VOC. The end-point of this problem based research is to create user requirements for the CDS concept based on qualitative and quantitative input from various sources, including international groups of clinical end-users. This research also utilized the Lean-based Fastworks process. The research started with a review of CDS in literature.

5.2 Data collection plan

Data was collected for this study using qualitative methods. There were four planned methods of data collection: literature review, focus groups (n=5), surveys, and learning diary. The details of the data collection plans are listed in the following sections.

5.2.1 Voice of customer collection plan

VOC can be collected from the end-user in many forms. In order to discuss VOC product needs and concept perception, the focus group approach can be used (Gryna 2000: Section 18; Lagrosen 2005: 433 - 434). The focus group method for collecting user feedback also has the potential for a more positive outcome than a one-on-one meeting, in that it saves time (all participate in a simultaneous session versus individual interviews), a record of the discussion is produced, and the entire process requires minimum investment by the company, yet it has the potential for significant benefit

(Gryna in Juran 2000: Section 18). It was decided to utilize the focus groups as the method to obtain VOC for the CDS concept. As the proposed clinical area of CDS utilization was hospital units with multi-parameter monitoring, the focus groups' membership was limited to clinicians with knowledge from these clinical areas. The focus groups were planned to be coming from a global audience.

5.2.2 Survey plan

In cases where there would not be any live, in-person contact with the focus groups, focus group tailored surveys would be used. The survey would be the data collection method for planned focus group webcast sessions. To support the use of the surveys, a PowerPoint presentation would be made and presented focusing on CDS as new technology.

5.2.3 Appropriateness of timing

VOC collection can begin even before a customer is even aware of the impending product, improvement, or need (Detrano in Juran 2000: Section 28). During the early phase of CDS development, small engineering teams planned to meet with the clinical end-users, our eventual customers, in order to understand their needs and current practice. The appropriateness of this early user involvement and interaction with engineering teams is supported by Stefan Lagrosen's (2005: 433) proposed level of relationship framework for customer involvement in new product development (Chart 3).

Framework for Customer Involvement with R&D				
Level of relationship	Longitudinal customer involvement	Lateral customer involvement	Suitable methods	Practical implementation
Transactional	Only in early phases	Design for the customer	Surveys Focus group interviews Observation	Current focus groups with moderated brainstorming and surveys.
Facilitative	In the early phases, in the testing phases, occasionally in other phases	Design with the customer	Quality function deployment, Delphi method, conjoint analysis, prototype testing, team customer visits	Usability testing, product team visitation to clinical sites, preference probing with prototypes, early stage hospital testing

Framework for Customer Involvement with R&D				
Level of relationship	Longitudinal customer involvement	Lateral customer involvement	Suitable methods	Practical implementation
Integrated	In all phases	Design by the customer	Integrated product development teams including representatives of both the supplier and the customer	Clinical evaluation, Clinical development studies, Concept testing, Validation testing

Chart 3: A framework for Customer Involvement with R&D is presented. The three levels of relationship are described by Lagrosen (2005: 433) and appended with a "practical implementation" column by the researcher.

In accordance with Lagrosen's framework, the user input was obtained from select focus groups during the transactional level of product development (Chart 3). This early interaction creates an integrative relationship between the customer and the company (Lagrosen 2005: 434). This transactional level cooperation is by definition limited to the engineering process phases T0 through T1.1 (Figure 10).

5.3 Learning diary plan

It was planned that the researcher would keep a learning diary. The use of the learning diary was planned as a personal recording method for events and personal reflection.

5.4 Analysis plan

All collected data would be analysed off-line using the induction method. The researcher would gather the data from the five focus groups. Data sources would include survey answers, free-from responses, and focus group transcripts. After this, the qualitative and quantitative data would be divided into themes. The similarities per theme, further divided into patterns and categories, would be manually analysed and results would be stated in the findings. Information gathered from the literature review would be used to compare and contrast to the focus groups' responses to the findings discussed in literature review. Any potential linkages between themes would also be explored. The Survey Central tool used to create the surveys includes a SPSS-type of predictive analytics program which also would be used for post-survey data analysis. The results would also be reviewed within the engineering program.

6 Ethical considerations

There were no ethical conflicts due to or related to this research. The following sections relate to the ethical considerations of this research.

6.1 Researcher's role

The researcher has a long, established clinical background. However, the researcher has not worked in a clinical setting for many years. The researcher has been working at the company in product development and installed base management for many years. During this research, the researcher was a part of a research group at the company in the role of Master's Thesis student.

6.2 Transparency

During all of the focus group meetings, the clinical and engineering working background of the researcher was disclosed to the participants. All groups were also made aware that the researcher was functioning as a part of the research team, and was both an observer and a data collector.

6.3 Non-disclosure

The sensitive research and development topics would be legally bound to confidentiality by the use of a non-disclosure agreement (NDA). Each company external focus group member would have to sign an NDA with the company before focus group participation. The NDA was either obtained by the researcher (CAB F1, CAB F2) or existed and in effect (CAB F4, CAB F5). One copy of the NDA was retained by the individual focus group member and one copy of the NDA was retained on file at the company's legal department. CAB F3 participants were employees of the company and are bound by its rules and regulations for ethical behavior and non-disclosure.

6.4 Review of conflicts of interest

By coincidence, CAB F1 included two members the researcher was familiar with professionally. There had been a timespan of at least ten years since the last collaboration took place, so this prior collaboration was considered to be non-

consequential and there were no conflicts of interest. CAB F2, CAB F4 and CAB F5 did not present any conflict of interest issues.

In summary, there were no conflicts of interest during the study. There was no influencing due to past professional familiarity between the researcher and some of the CAB members.

6.5 Financial aspects

Both Lagrosen (2005: 431) and Demir (et al 2012: 18) warn that the solicitation of user input can be costly, both in terms of time and finance. This, however, was not the case in these instances; none of the CAB focus group participants received monetary compensation for participation and time was set aside specifically for the purpose of focus groups interaction. Gryna's affordable approach to focus groups was actualized (in Juran 2000: Section 18). The use of a web-based survey did not incur cost to the research group.

6.6 Language

CAB F3 and CAB F5 data collection was in English; CAB F1, CAB F2, and CAB F4 data collection was in Finnish. The fully bilingual researcher translated the Finnish transcripts from Finnish to English. The translated transcript records of the focus groups were reviewed for accuracy by company participants. Translations and original language text used in this report are presented together.

6.7 Focus group anonymity

The focus group participants were informed that they would be de-identified in the transcribed record; individual responses were linked to the respondent by a coded number. The linkage of the coded numbers to the individual participant identification was stored separately from the transcription. Survey answers were anonymous and stored on the survey site.

7 Operative framework

The following sections detail the operating framework for VOC collection based on the research plan. The following are discussed: preparatory work, recording methods, focus group operative framework, and survey preparatory work. The learning diary was used as a tool during this phase; it is not discussed separately.

7.1 Focus group preparatory work

The company approached a key opinion leader (KOL) at a large university hospital and discussed the possibility of creating peer focus groups for the purpose of this research. It was agreed that the KOL, an M.D. and PhD, would serve as the focus group coordinator. Three focus groups were created (CAB F1, CAB F2, and CAB F4). The composition of these focus groups was fully controlled by the focus group coordinator. Thus, there was no influence on the composition of the two focus groups by the researcher or the research team; the focus group composition was a non-biased forum. The focus group coordinator met with the researcher and other company representatives prior to the focus group meetings to plan the practicalities of the focus group meetings.

CAB F3 participants were a convenience sample. They belong to an established, company sponsored nursing-led initiative called the Clinical Innovation Council (CIC). CIC members have clinical backgrounds and are employed by the company. The group is USA based, yet has a global membership. The members participate in scheduled, monthly, virtual meetings. The January 2014 meeting had the CDS topic as the agenda item. Two virtual preparatory meetings took place before the live event.

CAB F5 members were a part of a regularly scheduled advisory board virtual meeting with CDS as the agenda item. The framework is presented in Figure 16. The session was repeated twice during the day, related to time-zone differences of the participants. Due to the much smaller participant amount, each participant was able to present views during the question and answer session. The researcher manually recorded the virtual sessions.

7.2 Recording methods

Taping or filming the focus group was not viewed as an option for both technical reasons, and the researcher also felt individual responses may get “lost” or

misidentified during the group discussions if a recorded, non-individually focused, multi-participant format were to be utilized. As there was no focus group testing or concept analysis during this early point of product development, it was agreed by the program that transcription would be an appropriate data collection methodology for three of the focus groups (CAB F1, CAB F2, CAB F4), and a transcribed webcast with a follow-up web-based survey would be an appropriate data capture method for two focus groups (CAB F3, CAB F5). For CAB F1 and CAB F2, the researcher acted as a transcriber of the discussions. During CAB F4, a usability expert acted as the transcriber.

7.3 Focus group operative framework

It was decided by the research group that the best way to explore innovative ideas with CAB F1, CAB F2, and CAB F4 participants was to operate in a semi-structured fashion (Figure 14). The sessions were facilitated by a company moderator[1]. The focus group sessions were attended by company observers, which is an accepted practice (Gryna in Juran 2000: Section 18).

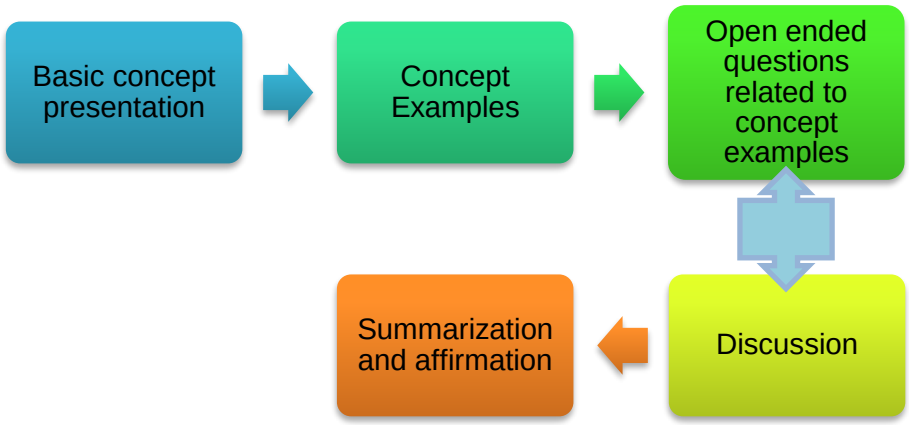


Figure 14: The framework of facilitated semi-structured VOC collection (by researcher).

The participants were encouraged to brainstorm freely around the focus areas. Focus groups CAB F1 and CAB F2 were started with KOL coordinator encouragement for the

[1] During CAB F1 and CAB F2, the focus groups sat either in a U-formation (CAB F2) or in a parallel preparatory formation to one another (CAB F1) in order to encourage participation. CAB F4 was a focus group meeting with the same operational functionality as CAB F1 and CAB F2; all participants sat at the same table. So as not to influence the focus groups' discussions, the researcher sat separately from the focus groups.

members to actively "practice shouting out comments" (*Finnish: "harrastetaan aktiivista ylihuutoa"*). CAB F4 was a small-scale, interactive session.

During CAB F3, the researcher had an active role as the sole presenter during the webcast; the session was a one-way flow presentation (Appendix 1) by the researcher with a follow-up question and answer session. The operative framework for CAB F3 is in Figure 15.

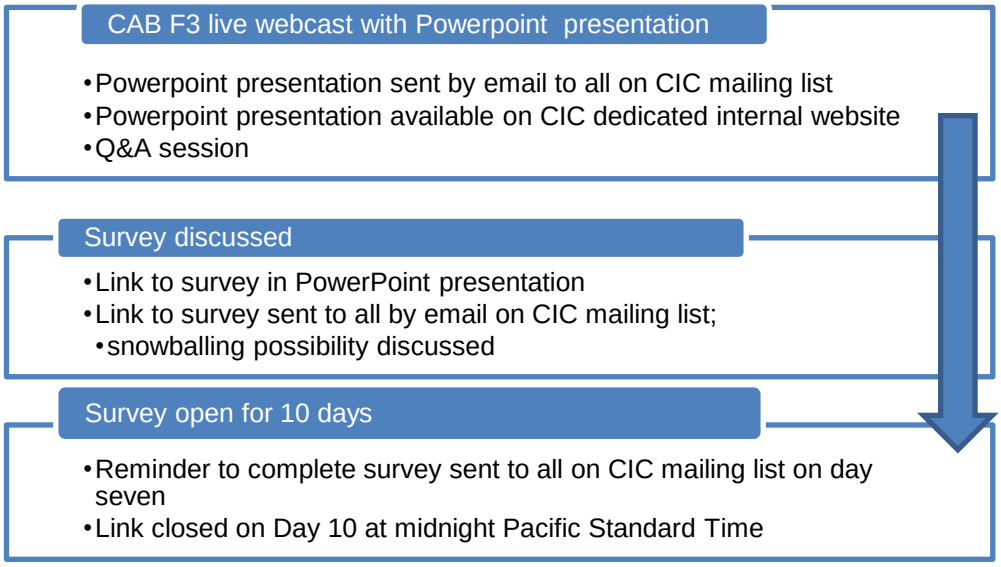


Figure 15: The operative framework of the didactic VOC collection with CAB F3 (by researcher).

CAB F5 was a global, virtual session and follow-up web survey. Due to global time-zone issues, CAB F5 was held as two identical sessions during the same day. The operative framework is presented in Figure 16.

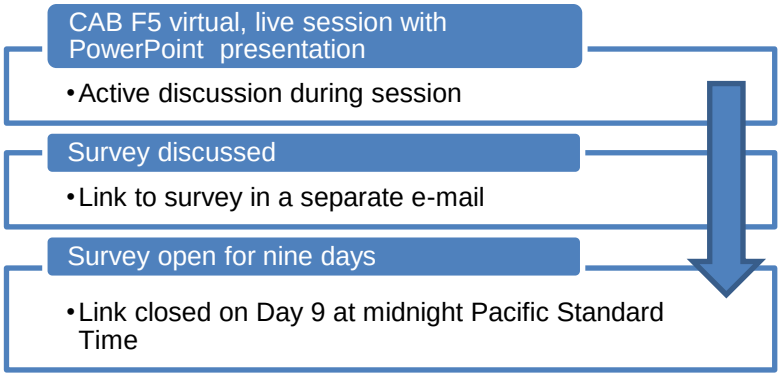


Figure 16: The operative framework of the didactic VOC collection with CAB F5 (by researcher).

Both CAB F3[2] and CAB F5 were supported by a follow-up survey (Appendix 2 and Appendix 3, respectively). Survey feedback was produced as raw data and summarization was automated by the survey tool and disseminated by the researcher.

7.4 Survey preparatory work

The survey was designed by the researcher using factors for consideration in survey design (Ary, Jacobs, and Sorensen 2010: 395; Demir et al 2012: 75 - 78; Crouch et al 2012: 131 - 141). The survey for CAB F3 (Appendix 2) was created after CAB F1 and CAB F2 were held, so there was an opportunity for reflection during the survey's creation. Constructive criticism related to the survey was solicited from the program team.

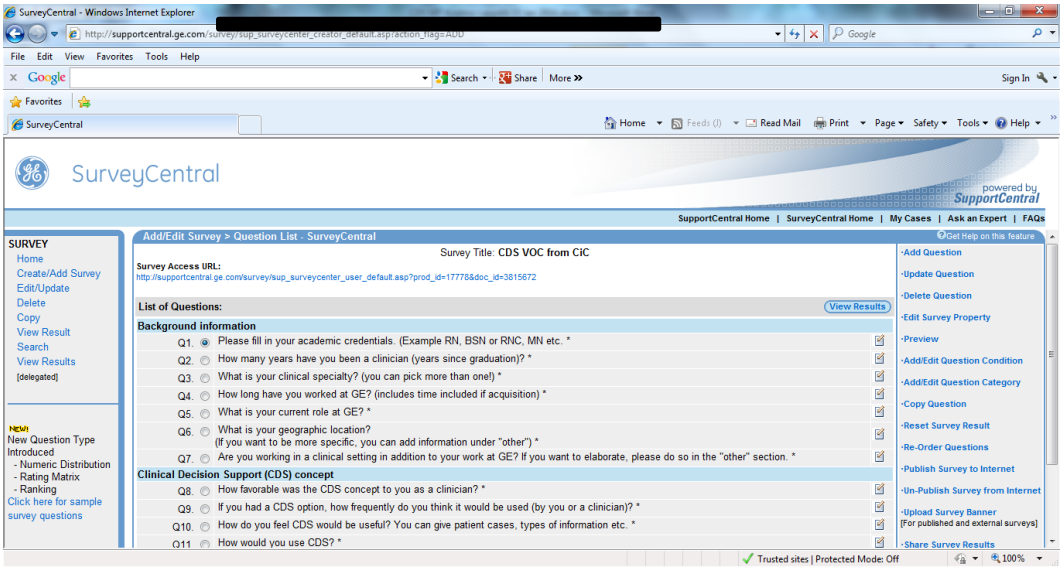


Figure 17: Screen view shot of the Survey Central site with the survey work in progress.

The tool used to create the surveys was the company's official web-based interface for creating qualitative and quantitative web surveys, called "Survey Central" (Figure 17). The survey consisted of quantitative and qualitative data collection methods: open-ended questions, Likert-like scale responses, multiple choice questions, and option rate ranking were utilized. The survey responses were anonymous. The survey was meant to be used after an introductory CDS concept PowerPoint presentation by the

[2] The webcast participants were also given the opportunity to invite other company internal clinicians to participate, thus creating the potential for a snowball effect. Twelve computers were linked to the webcast, yet 25 responded to the survey. It appears that the snowballing was effective, although many people may have been using a computer to participate in the webcast.

researcher (Appendix 1). This was the first time Survey Central was used to capture user needs and requirements.

As Survey Central's use was seen as beneficial, the web survey tool was utilized again for CAB F5 data collection. They survey's composition was similar to CAB F3's survey. The focus of the survey was for use of the CDS tool in the anesthesia and PACU units by anesthesiologists (Appendix 3). The respondents (n=4) were non-company employees, so this time the survey would have a new dimension: a company external web-link. The research questions were created by the research team.

8 Outcomes and analysis

The data collection actualized per plan. The following sub-sections are the evaluation of the findings using inductive content analysis of the data. The analysis starts with a Fastworks summary. After the Fastworks summary section, each of the CAB are discussed, and the input is analyzed for each CAB.

8.1 Fastworks summary

The Fastworks summary of the five CAB groups is presented in Chart 4. The analysis of the Fastworks data is presented in the following sections, including pivot and persevere points. The minimum viable product (MVP) is the input method(s) or the session.

CDS FASTWORKS SUMMARY FOR CAB GROUPS F1 – F5					
MVP, learning matrix identification	**Goals of session**	**CDS Fastworks session theme**	**Persevere**	**Pivot**	**Notes**
CAB F1					
Power-Point presenta-tion of initial concept Prototype screen-views	To: gauge response-vity to the concept potentially identify basic user needs to build on in future sessions	Concept feasibility	Persevere	Pivot: Professional group usage may be different -> *explore professional usage*	First time the concept had been shown to any company-external clinicians; concept was well accepted. Novel screen view prototypes were well accepted.
		Visualization preferences	Persevere	Pivot: ICU and Anesthesia environments may have different needs -> *explore environment needs*	
CAB F2					
Prototype screen-views Power-Point presenta-tion of	to flush out more information related to clinical area needs to receive	CDS use in the ICU vs anesthesia units	Persevere	No pivot	Verification of CAB F1 pivot that ICU and Anesthesia environments need CDS, yet appear to have different needs
		Current use of monitor and trending and future potential	Persevere	No pivot	

CDS FASTWORKS SUMMARY FOR CAB GROUPS F1 – F5					
MVP, learning matrix identification	**Goals of session**	**CDS Fastworks session theme**	**Persevere**	**Pivot**	**Notes**
current CDS concept	feedback related to prototype screen views	with CDS			*Persevere-> explore with multi-professional and international focus groups from various care areas.* CDS concept adaptability to clinical situation (PMI) evaluated, and concept is deemed feasible for multiparameter monitoring.
CAB F3					
Power-Point presenta-tion of current concept Prototype screen-views Survey 1	Include multi-profes-sional, interna-tional viewpoint and scope	Usefulness and utility of the CDS	Persevere	No pivot	International group of mixed clinicians from various care areas. First time survey was utilized Professional usage boundaries and touch points assessed. Can continue to verify the UR from this sample: UR based on input from CAB F1 and CAB F2 now ranked Assessed that the application is needed and its potential use (can be used in validation testing)
		Professional usage boundaries and touch points	Persevere	No pivot	
		User requirements	Persevere	No pivot	
		Application of CDS	Persevere	No pivot	
CAB F4					
Power-Point presenta-tion of	Discuss clinical setting differences	Ideal monitoring system	Persevere	No pivot	New prototypes well received, new ideas brainstormed.
		Clinical setting	Persevere	No pivot	

CDS FASTWORKS SUMMARY FOR CAB GROUPS F1 – F5					
MVP, learning matrix identification	**Goals of session**	**CDS Fastworks session theme**	**Persevere**	**Pivot**	**Notes**
current concept Prototype screen-views	(clarify, based on input from three previous sessions) New prototype screen view assess-ment	difference			
		Trend display preferences	Persevere	No pivot	Verification of clinical setting differences (determined in CAB F3)
CAB F5					
Power-Point presenta-tion of current concept Prototype screen-views Survey 2	Focus on anesthesiol ogist usage – internation al base of expert users PACU vs Anesthesia differences	Mobile application	Persevere	Pivot: assess type of device, usability with design on screen, user usage.	PACU vs Anesthesia use and differences are the focus, clarification received, mirrors CAB F3 and CAB F4 results. PACU needs similar to ICU, yet shorter term. Second time survey used for gathering input Mobile device – more MD focus? Size/cleaning/etc. - issues to investigate.
		CDS views and use	Persevere	No pivot	
		PACU and Anesthesia differences	Persevere	Pivot: PACU and anesthesia are different	

Chart 4: Fastworks summary for the CDS concept CAB input

The Fastworks sessions were iterative and built the CDS concept based on the previous session. The results helped guide the team in building on the concept and provided valuable input for the prototype design. Each Fastworks session built on the former sessions and served as a springboard for new ideas.

8.1.1 Fastworks initial assumptions versus results

The following is a Fastworks summary outcome of the initial leap of faith assumptions versus the results obtained during this research. The initial leap of faith assumptions are followed by the result.

1. CDS would be accepted as a concept by the users: Assumption supported by data.
2. Professional groups (physicians/nurses) would use the CDS in the same way: Assumption not supported by data.
3. CDS potential solution would include solution-specific concepts:
    a. provision of building blocks: Assumption supported by data.
    b. build-it-yourself application: Assumption supported by data

The analysis is in the following sections.

8.2 Focus group composition

International clinicians (n=53) were solicited for VOC user input data collection for the CDS concept during six separate occasions. The makeup of the focus groups was as suggested by Gryna (in Juran (ed.) 2000: section 18). Summaries of the focus group compositions are found in Chart 5 and CAB breakdown in Chart 6.

Focus group composition, all CAB

Group ID	Session date	Physicians	Nurses	Respi-ratory	Length of session and survey completion time (est)	Session sites	Method of participation
CAB F1	Sept 11 2013	11	1	0	2 hours focus group no survey	Finland	Face to face
CAB F2	Nov 28 2013	8	0	0	2 hours focus group no survey	Finland	Face to face
CAB F3	Jan 28 2014	3	20	2	30 minute interactive lecture 12.5 hours survey	Global	Web and Teleconference based, Survey

Group ID	Session date	Physi cians	Nurses	Respi-ratory	Length of session and survey completion time (est)	Session sites	Method of participation
CAB F4	Feb 25 2014	3	0	0	4 hours focus group no survey	Finland	Face to face
CAB F5	March 20 2014	5	0	0	4 hours focus group (in two, two hour sessions) 2 hours survey	Global	Web and Teleconference based, Survey
Sum-mary	Sept 2013 – March 2014	30	21	2	12.5 hours of focus group 14.5 hours survey	Global forum	Face to face and virtual sessions, survey
Totals	Five ses-sions	53 participants representing 3 professional fields			~27 hours total for focus group and survey completion	Global forum	Face to face and virtual sessions, Surveys

Chart 5: Summary of focus group composition and data collection for the five CAB sessions.

Focus group data collection involved the two major user groups, physicians and nurses (Figure 18). In addition to these two roles, there were two respiratory specialists whose role is much like that of a nurse, except that their education and responsibility are focused on respiratory issues. The input of the respiratory specialists was analysed as nurse input category, as respiratory therapists provide interventional care much in the same manner as nurses do. Respiratory therapy is not an internationally known profession, so their input was, in that way, unique and valuable.

Summary of all CAB participants			
Event ID	**Title (role)**	**Specialty area or role, self-reported**	**Relationship group**
CAB F 1	MD	Anesthesiology	current, special customers
CAB F 1	MD	Anesthesiology & IT	current, special customers
CAB F 1	MD	Anesthesiology	current, special customers
CAB F 1	MD	Med Director	current, special customers
CAB F 1	MD	ICU	current, special customers
CAB F 1	MD	ICU	current, special customers
CAB F 1	MD	Anesthesiology	current, special customers
CAB F 1	MD	ICU	current, special customers
CAB F 1	RN	ICU	current, special customers
CAB F 1	MD	ICU	current, special customers
CAB F 1	MD	Anesthesiology	current, special customers

Summary of all CAB participants			
Event ID	**Title (role)**	**Specialty area or role, self-reported**	**Relationship group**
CAB F 1	MD	ICU	current, special customers
CAB F 2	MD	Anesthesiology	current, special customers
CAB F 2	MD	Anesthesiology	current, special customers
CAB F 2	MD	ICU	current, special customers
CAB F 2	MD	Anesthesiology	current, special customers
CAB F 2	MD	ICU	current, special customers
CAB F 2	MD	Anesthesiology	current, special customers
CAB F 2	MD	Anesthesiology	current, special customers
CAB F 2	MD	Anesthesiology	current, special customers
CAB F3	RN	Cardiac ICU, ICU, Medical / Surgical, Research	company internal employees
CAB F3	RN	ER /Trauma, NICU, Transport/flight	company internal employees
CAB F3	RN	ER /Trauma, Medical / Surgical, Long Term Acute Care, Nursing Leadership	company internal employees
CAB F3	RN	Anesthesia (includes all areas, adult), ICU, ER /Trauma, Transport/flight, Step-down, Neurology	company internal employees
CAB F3	RT	Cardiac ICU, ICU, ER /Trauma, Medical / Surgical	company internal employees
CAB F3	RN	Anesthesia (includes all areas, adult), Anesthesia (includes all areas, pediatrics), Cardiac ICU, ICU, ER /Trauma, PICU, NICU, Medical / Surgical, Transport/flight, Step-down, Neurology	company internal employees
CAB F3	MD	Anesthesia (includes all areas, adult), Anesthesia (includes all areas, pediatrics)	company internal employees
CAB F3	RN	ICU	company internal employees
CAB F3	RN	Anesthesia (includes all areas, adult), Anesthesia (includes all areas, pediatrics), ICU, ER /Trauma	company internal employees
CAB F3	MD	ER /Trauma	company internal employees
CAB F3	RN	NICU	company internal employees
CAB F3	RN	Cardiac ICU, ICU, ER /Trauma, Medical / Surgical	company internal employees
CAB F3	RN	Cardiac ICU, ICU, ER /Trauma	company internal employees
CAB F3	RN	Anesthesia (includes all areas, adult), ICU	company internal employees
CAB F3	RN	Cardiac ICU	company internal employees
CAB F3	MD	ICU, ER /Trauma, Medical / Surgical	company internal employees
CAB F3	RN	Anesthesia (includes all areas, adult), Anesthesia (includes all areas, pediatrics), ER /Trauma	company internal employees
CAB F3	RN	Cardiac ICU, ICU, ER /Trauma	company internal employees
CAB F3	RN	Cardiac ICU, ICU	company internal employees
CAB F3	RN	Step-down	company internal employees
CAB F3	RN	Anesthesia (includes all areas, adult), ICU	company internal employees
CAB F3	RN	NICU, OB GYN/ L&D, NBN, Pediatrics	company internal employees
CAB F3	RN	Cardiac ICU, ICU, ER /Trauma, Medical / Surgical, Burn ICU, Urgent Care	company internal employees
CAB F3	RN	Anesthesia (includes all areas, adult), ER /Trauma, Medical / Surgical, plastic surgery	company internal employees
CAB F3	Anesthesia technician	Anesthesia (includes all areas, adult), Anesthesia (includes all areas, pediatrics)	company internal employees
CAB F4	MD	Anesthesia	current, special customers
CAB F4	MD	Anesthesia, ICU	current, special customers

Summary of all CAB participants			
Event ID	**Title (role)**	**Specialty area or role, self-reported**	**Relationship group**
CAB F4	MD	ICU, Anesthesiology	current, special customers
CAB F5	MD	Anesthesiology and PACU	current, special customers
CAB F5	MD	Anesthesiology and PACU	current, special customers
CAB F5	MD	Anesthesiology and PACU	current, special customers
CAB F5	MD	Anesthesiology and PACU	current, special customers
CAB F5	MD	Anesthesiology and PACU	current, special customers

Chart 6: Demographical factors and CAB participation identification. MD indicates a physician, RN indicates a nurse. Respondents who were nurses had degrees ranging from basic level to post-Master's degree. All participants had active roles.

All CAB participant professional background

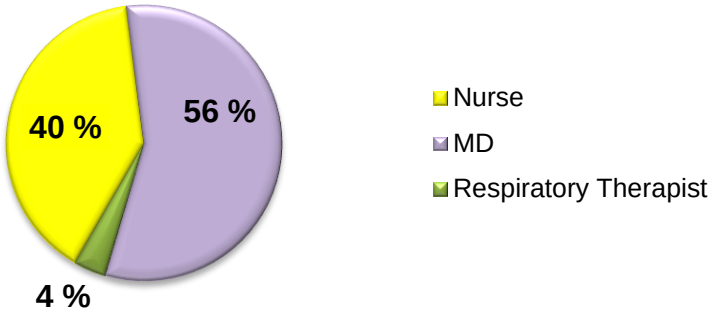


Figure 18: CAB F1 – CAB F5 professional makeup: 30 physicians, 21 nurses, and two respiratory therapists. n=53

The use of nurse and physician input was seen to increase the dynamics of the user input, as both groups use patient monitors. It was not known if nurses and physicians would use the CDS tool in similar or different ways. Additionally, care area differences were not known between the practitioners or geographical locations. This international approach also provided for not only data collection from a cross-cultural multi-professional group of individuals, but also could have revealed potentially different approaches to the same problems and challenges. The analysis on the input was used to create user requirements (UR).

8.3 Inductive analysis and results of CAB F1 input

The following sections are inductive analysis of the CAB F1 input. Responses were divided into themes and were analysed per theme. Direct quotations are presented in italics[3].

8.3.1 Demographics CAB F1

All of the respondents were from Finland and were in active, current practice as physicians (n=11) or as a nurse at the time of focus group participation. The participants practiced in many specialty hospitals within the same, large university hospital's umbrella. CAB F1 was composed of nine males and three females.

8.3.2 Results CAB F1 Theme 1: CDS as a concept

Feedback in general was very basic, as was expected for a first session. The concept was met with a surprisingly positive response. The respondents' statements were also reviewed after the session by the research team and ranked in traffic-light style. The predominant response level was "green light". Co-creation was a favored method, as the physicians pointed out that

> *engineers do not have the clinical knowledge, doctors are needed; clinical needs are new, always evolving…what to do and when this is something that needs to be developed together./ Insinöörit eivät omaa kliinistä asiantuntemusta, lääkäreitä tarvitaan; kliiniiset tarpeet ovat uusia, aina kehittymässä...mitä tehdä ja milloin on jotain, jota pitää kehittää yhdessä.*
>
> - Participant 1, CAB F1 (MD)

Beneficially for the research team, Participant 5 stated that there are staff members at the hospital who are interested in monitor development and keeping up on the cutting edge. This may be useful during later testing phases.

It was spontaneously stated by many members of CAB F1 that nurses and doctors would use the CDS differently. One of the physicians[4] proposed that the nurse would be using the monitor differently related to the experience and interest of the nurse. As there was only one nursing participant in CAB F1, the team decided that more nursing input was needed. The engineering group decided to investigate role usage differences further in future CAB sessions.

---

[3] Throughout the analysis, the term respondent refers to a survey question answer and the term participant refers to a focus group member; all are clinicians.

[4] Participant 6, CAB F1

8.3.3 Results CAB F1 Theme 2: CDS visualization preferences

CAB F1 was asked to comment on two potential, basic, mock CDS views in PowerPoint form. One mock-up was an anatomical representation of organs which would be potentially affected by the changing parameters, and the other was pure graphical representation of trends. It was asked if both of the views would be useful, or what would have to be changed to make the views useful.

Most of the participants did not like the organ view representation. It was determined that patient monitoring in effect is reduction; patients are not cared for related to pictures. "*Anatomical pictures do not give you any help or serve any purpose to the clinician/ anatomiset kuvat eivät auta sua yhtään, eikä niissä ole kliinikolle tarkoituksenmukaisuutta*"[5], yet the current monitoring solution was also not seen as adequate. There was one application for an anatomical picture and this was a neurological solution. It was suggested that different areas of the brain and its activity would be colored or shaded in relation to the brain's activity state.

These clinicians liked the "Bull's Eye" graphical representation and felt it was a good idea for visualization. Patient reactions to interventions were seen as an important item; this could potentially be viewed with trends. Trending curves/lines were seen in effect as important overall, in that

> *currently the monitor shows the momentary status of people and their care, the seconds and the follow-up are related to the same lines. The lines are not important, we need trends that make a difference/ Nykyään monitori näyttää hetkisen tilanteen ihmisistä ja niiden hoidosta, sekunnit ja niiden seuranta ovat suhteessa samoihin viivoihin. Viivat eivät ole tärkeitä, vaan tarvitsemme trendejä jotka erottuvat.*
>
> - Participant 10, CAB F1 (MD)

The clinicians agreed there was a need for better displays, and there is an improvement need in the ways the monitor shows information. The use of colors was also discussed. Participant 10 pondered if the screen could be simple green and black, with colors appearing only when there as a change in state. This would be a novel approach. Participant 5 stated the monitor could identify the user and create a profile for user, suggesting a thumb print identification or a fed code. He also felt that a speedometer is a clear visualization that could be used for CDS. The physician

[5] Participant 1, CAB F1

consensus was that they should not spend their time creating their own applications or views, even if building blocks were provided.

The participants were also shown a trend versus real time mock-up, in which screen view would have a varying percentage of real-time vs trended views. Also, the need for percent of retrospective trend time presentation on the screen was differing by care area. The anesthesia unit would need less trending time, as the patients are in the surgical suite for a relatively short time (hours), while the patient is cared for in the ICU for a longer time (days to weeks). It became evident that the engineering team would have to pay attention to scaling, as scaling needs of clinicians were different from what the monitor is currently able to present and would be also different related to the care area. ICU clinicians desired a longer trending period.

One participant stated he was glad the team was not bringing a new parameter or measurement method for CAB evaluation. The team was presenting something new, something that was needed:

> *No new parameters are needed, we need to understand how to control and manage the chaos of all the information – give information to the users. / Uusia parametreja ei tarvita – vaan tarvitaan ymmärtämistä, miten käyttäjille kontrolloidana ja hallinoidaan kaaoottista informaatiota.*
>
> - Participant 1, CAB F1 (MD)

This statement was a positive reflection of the earlier stated strategic decision to not provide a new parameter, but to work on analytics in the form of data presentation.

8.4 Inductive analysis and results of CAB F2 input

The following sections are an inductive analysis and results of the CAB F2 input. Responses were divided into themes and were analysed per theme. Direct quotations are presented in italics.

8.4.1 Demographics CAB F2

All of the participants were from Finland and were in active, current practice as physicians (n=8) at the time of focus group participation. The participants practiced in many specialty hospitals within the same, large university hospital's umbrella. CAB F2 was composed of five males and three females.

8.4.2 Results CAB F2 Theme 1: ICU and Anesthesia unit differences

CAB F2 were shown a mock-up of a patient screen with real time data, and colored blocks decreasing the amount of visible real-time data to either 20% of the screen, 50% of the screen, or the entire screen. The colored block represented trend data which would be shown before transitioning to real-time data. The participants were asked two factors related to these representation styles: what percentage of trends versus real time screen view would they prefer, and in what clinical context would the views be appropriate.

The participants all stated that the anesthesia and ICUs would require different types of screen views, and would require different types of real-time versus trended data.

> *I would like the trend to be more of the real time data, but it has to be flexible. It is not good to have 2/3 of the screen covered for a one hour surgery. If there are 12 hours of events, then it is OK. / Haluaisin, että on enemmän trendiä kuin reaaliaikadataa, mutta sen on oltava joustavaa. Jos on tunnin kestävä leikkaus, 2/3-osa peitettynä ei ole hyvä. Jos tapahtumaa 12-tunnin verran, sitten se on ihan OK.*
>
> - Participant 5, CAB F3 (MD)

Some anesthesiologists were of the opinion there was

> *no need to trend changes to time scale, if you have an open heart surgery, the real time events are more important. Other times, trends could be shown elsewhere. / Ei ole tarvetta trendata aikaskaalaa vastaan, jos on avosydänleikkaus, reaaliaikatapahtumat ovat paljon tärkeämpiä. Muulloin, trendejä voisi näyttää muualla.*
>
> - Participant 7, CAB F3 (MD)

The intensive care physicians saw the need for trending, as their care is longer-term than that of the anesthesia department. One specific example of a septic patient was given and the need to see the weak signals (heikot signaalit) that are not now visible on the monitoring screen. "*The trends and the weak signals need to be realized/ trendit ja heikot signaalit pitää realisoida*"[6] in the ICU, where care is based in part on trending. The prevailing view trends are for seeing the real time data and how it changed in the patient state, and the clinician is looking for subtle changes in these trends. With an ICU patient, it appeared that a ¾ trend and ¼ real time screen view would be clinically appropriate.

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[6] Participant 1, CAB F3

8.4.3 Results CAB F2 Theme 2: Current use and future potential

The first comment was that "*the current monitor is quite OK/ nykyinen monitori on aika OK",* but this same participant quickly countered himself by saying,

> *when looking at the OR versus the ICU, it is different. Usually in the OR, the physical context of the happenings is attainable; if an open heart surgery or other…a laparoscopy, abdominal pressure is rising – there is a lot happening and the anesthesiologist doesn't notice them then something could happen./ Kun katsotaan leikkuria versus ICU:a, se on erilaista. Yleensä leikkurissa, se fyysinen konteksti, mitä siinä tapahtuu on saatavana; jos on avosydänleikkaus tai joku muu...laparotomia, vatsan paineet nousevat – paljon tapahtuu ja jos anestesiologi ei huomaa niitä, niin jotain voi tapahtua*.
>
> - Participant 1, CAB F2 (MD)

From his statement, we can see that he relies on many other things, even his own senses, for a monitoring view of the patient. Participant 7 validated this view by saying, "*there is not one solution for all, you have to look at the surgeon, other monitors/ ei ole yksiselitteinen sovellus, pitää katsella kirurgia, muita monitoreita*".

The CDS features would be either pre-configured for a standard view or customized by the user. Compared to the current solution, the need was to have "*good screen views graphically, easier to use – more graphics…for example with ECG, I suggest a simpler design. / ruudun graafinen näkymähän pitää olla hyvä, helpompi käyttää – lisää graafisuutta…esimerkiksi ECG:n suhteen, ehdotan helpompaa muotoilua"*[7] Even the globally recognized and solely used squiggly ECG presentation is not seen as useful.

8.4.4 Analysis of PMI cardiac event and CDS input feasibility

During CAB F2, the participants stressed how important it would be to recognize perioperative myocardial infarctions (PMI) and that the opportunity for better, case-flow PMI related design is grossly evident. Salmenperä, Petäjä and Virolainen reported that PMI is an underdiagnosed, negative myocardial event associated with the peri-operative and post-operative period. It brings with it a significant restriction on the outcome of the operative treatment and carries a high mortality rate. PMI-induced death rate estimates range from 10 - 25% in effected surgical patients. PMI occurs in 0.5 – 1% of the general surgical population but can rise to one in ten cases during high

[7] Participant 1, CAB F3

risk surgical procedures. PMI brings with it an approximate 11 extra hospitalization days per person, and the risk of associated death is greater (2013: 2229 – 2236).

It was argued that optimization of data presentation could improve patient outcome – as currently there is no solution. With an improvement in data presentation, the creation of a CDS Level II PMI view for anesthesia patients could provide early identification of the currently undiagnosed condition of PMI. This early recognition could result in increased quality of life for the patient and great economical savings of direct and indirect costs. In Finland alone, post-PMI treatment requires at least 20,000 additional hospitalization days[8] (Salmenperä et al 2013: 2229). In theory, the use of even a CDS Level II solution could provide early detection and decrease extra PMI hospitalization days. The benefits of early recognition PMI CDS could have a savings effect on hospital costs. Using average 2014 costs for a solely intensive care day in a Finnish university hospital with no other services or interventions (Helsingin ja Uudenmaan Sairaanhoitopiiri 2014: 1 – 440), theoretical PMI-related savings of just additional hospital days alone are measured at a minimum of 64 million Euro for solely PMI in 2014.

As there is no way to predict PMI, early recognition and early intervention are the only available options. Early identification and intervention could prevent or decrease the plethora of negative PMI outcomes (including death). Finding the optimal way of presenting data could assist in early identification of events such as PMI, therefore decreasing negative outcomes, including costly extra hospitalization days.

The researcher analysed the components of PMI and compared them to the monitor and the CDS concept for feasibility. The parameters to identify PMI are available in the company's multiparameter monitor. The grouping of the data, along with a usability analysis could provide an early indicator of PMI. The example of PMI CDS rule-based input requirements is presented in Figure 19.

This listing is an example of PMI CDS rule-based input for decision framework using patient monitor input for clinical utility in non-cardiac case perioperative patients.
*** denotes potential alarm states*

A .Input Age [*clinician (manual) or EHR (automatic, verified) input]*
B. Input Gender [*clinician (manual) or EHR (automatic, verified) input]*
C. For a PMI risk ranking index, assess per Lee's revised cardiac risk index:

[8] adjusted per population in Finland

[*clinician (manual) or EHR (automatic, verified) input]*

Select all applicable :

C1. History of ischemic heart disease
C2. History of congestive heart failure
C3. History of cerebrovascular disease (stroke or transient ischemic attack)
C4. History of diabetes requiring preoperative insulin use
C5. Chronic kidney disease (creatinine > 2 mg/dL)
C6. Undergoing suprainguinal vascular, intraperitoneal, or intrathoracic surgery

Risk for cardiac death, non-fatal myocardial infarction, and non-fatal cardiac arrest:

- 0 predictors = 0.4%,
- 1 predictor = 0.9%,
- 2 predictors = 6.6%,
- ≥3 predictors = >11%

AND

clinical history of hemorrhaging during surgery (secondary anemia) YES/NO * [*clinician (manual) or EHR (automatic, verified) input]*

D. Monitor would be programmed with a PMI application / workspace based on the following:

Clinical signs/symptoms

- Hypo/hypertension (NIBP, invBP, pp) **
- Excessive bleeding during surgery (secondary anemia)
- Heart failure
- Pulse wave increases in size and frequency
- ECG changes **:
  - Atrial fibrillation
  - Tachycardia (especially triggered at >10 bpm increase)
  - ST-wave increases:
    - ST-rise@ J-point > 0,1 mV in two adjacent leads, if V2 and V3, then
      - 0,2 mV rise in men* > 40 y
      - 0,25 mV rise in men* < 40 year
      - 0,15 mV rise on females*
  - ST-wave decrease and T-wave inversions:
    - New horizontals OR decreasing ST-decreasing at the J-point 0,05 mV in two adjacent leads
    - T-inversion > 0.1 in two adjacent leads with R and S wave relationship >1

Note for probability factoring, the rate of common ECG changes is as follows:

- 12% present with a Q-wave
- 10% present with a ST rise
- 31% present with a ST depression
- 22% present with T-wave inversion

and these anomalies should be considered for automatic, change from baseline ECG alerts.

Note: not valid if left branch bundle block (LBBB diagnosis), changes can't be evaluated – because LBBB surgery will produce an infarction diagnosis in any case.*

Figure 19: Example of PMI CDS rule-based input for decision framework using patient monitor input for clinical utility in non-cardiac case perioperative patients; Tailored CDS Level II data input for PMI by researcher. Figure of framework by researcher, based on Salmenperä (2013) and the Revised Cardiac Risk Index by Lee as in Fleisher, Beckman, Brown, Calkins, Chaikof, Fleischmann, Freeman, Froehlich, Kasper, Kersten, Riegel, and Robb (2007).

CDS for PMI could decrease or eliminate the amount and severity of the associated PMI sequela and provide economic benefit. CDS would be feasible in this type of clinical scenario.

8.5 Inductive analysis and results of the CAB F3 input

The following section is the inductive analysis of the CAB F3 survey results. Responses were divided into themes and were analysed per theme. Direct quotations are presented in italics. Respondents provided written answers in English, which for many was not their mother language. The responses may be in non-standard English and are not edited by the researcher except to foster readability or clarity.

8.5.1 CAB F3 Demographics

One of the main purposes for utilizing the CIC network was its international base of clinicians. As CAB F1 and CAB F2 focused primarily on Finnish KOL physicians, other viewpoints were desired. The CIC is composed primarily of nurses and other hospital primary care providers and was an excellent venue as an international population

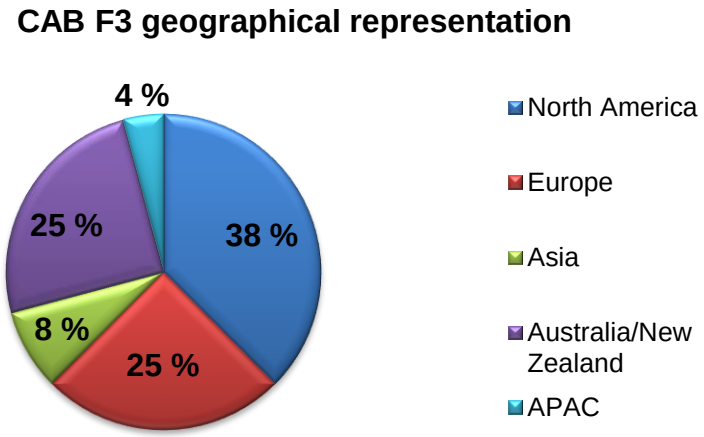


Figure 20: The CAB F3 respondents reported geographic location. (APAC region includes Australia, New Zealand, Japan, South Korea and all Southeast Asian countries). n=25

of healthcare providers (Figure 20). The greatest representation came from North America, as was hoped, with a nearly equal amount of Australia/New Zealand participants. There was no representation from Latin America, South America, or the Middle East. Africa was not included in the survey, as it was known there were no CIC members from Africa.

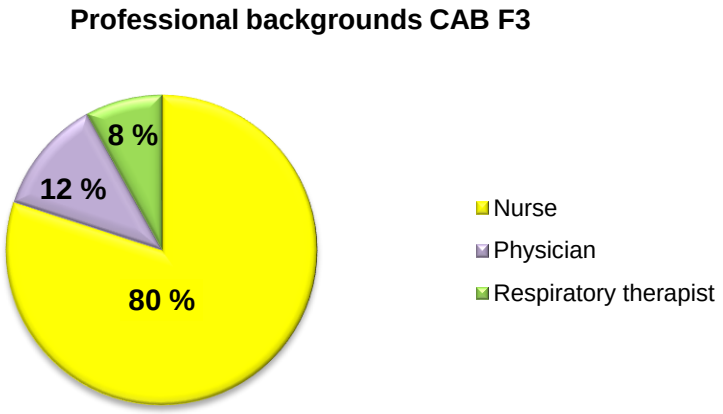


Figure 21: CAB F3 respondents' professions. n=25

Of the 25 respondents, nine were males (36%) and 16 were females (64%). The predominant view would be held by nurses (Figure 21), as was desired.

8.5.2 CAB F3 general

In response to the question how long the respondents have been clinicians, over half (56%, n=14) reported having at least twenty years since graduation as a clinician. The tenure at the company was also long, with 56% (n=14) reporting greater than 20 years tenure. Of this 56%, 28% (n=7) reported having tenure of over ten and under 20 years at the company.

Many of all respondents (24%, n=6) replied that they were working in a clinical setting in addition to or while working at the company. These factors were important to assess, in that the accrued clinical and healthcare business knowledge over time would give a broader view of clinical work and clinical needs: with time comes experience.

Areas of clinical specialization were assessed. The area of clinical specialization could have an effect on monitoring use. Figure 22 presents self-reported clinical specialties of the respondents by gender. Respondents were allowed to pick more than one clinical specialty area, as clinicians often multi-specialize and cross-train, and are therefore able to fluidly move from one unit to another.

Clinical specialties	Male	Female	**Total**
Anesthesia (includes all areas, adult)	6 **(60)%**	4 **(40)%**	**10**
Anesthesia (includes all	6	0	**6**

Clinical specialties	Male	Female	Total
areas, pediatrics)	(100)%	(0)%	
Cardiac ICU	3 (33.3)%	6 (66.7)%	9
ICU	5 (35.7)%	9 (64.3)%	14
ER /Trauma	7 (46.7)%	8 (53.3)%	15
PICU	1 (100)%	0 (0)%	1
NICU	1 (20)%	4 (80)%	5
Medical / Surgical	2 (25)%	6 (75)%	8
OB GYN/ L&D	0 (0)%	1 (100)%	1
Transport/flight	1 (33.3)%	2 (66.7)%	3
Step-down	1 (33.3)%	2 (66.7)%	3
Neurology	1 (50)%	1 (50)%	2
Totals	34	43	77

Figure 22: Breakdown of CAB F3 clinical specialty area by gender. 25 respondents reported 77 areas of clinical specialty.

The respondents were of international and multi-specialization background and thus could provide insight into potentially varied clinical practices. From these answers, it can be concluded that this international group has broad clinical experience to base their responses on.

8.5.3 Results CAB F3 Theme 1: CDS conceptualized

To assess the extent to which the clinicians are able to conceptualize change in a pre-existing solution, they were asked what they would change. The survey question number nine was designed to get a baseline opinion of current monitor features that could be improved. If the respondent would answer along the lines that ‘everything is fine’, or ‘no changes’ are required, their answers to the entire survey would have to be viewed as separate due to a potentially positive monitor bias. However, all of the clinicians did have improvement suggestions; separate analysis was not required. This question prompted long answers. It clearly was an item of relevance and importance to the clinicians. Although the field was opened to all suggestions, many clinicians stated that what is needed is a correlation of parameters to clinical picture. This could have been influenced by the presentation related to CDS, but it also validates the

overwhelmingly strong support for a CDS solution. The most supportive response was that CDS "*will revolutionalise patient* (and) *disease management workflow*"[9].

CDS concept favorability from a clinical viewpoint was ranked by the group as "quite" to "very interesting", scoring 44% (n=11) and 36% (n=9) respectively. This produced an overwhelming amount of clinicians rating the concept as "quite" to "very interesting" (total 80%), or nearly everyone (Figure 23). None of the clinicians reported having no interest in the concept, while 20% (n=5) were either "somewhat" interested" or "neutral" towards the concept. All of the clinicians reported some interest in the concept (Figure 23). From this, it can be proposed that the clinicians may have potential solutions, needs, and desires in mind.

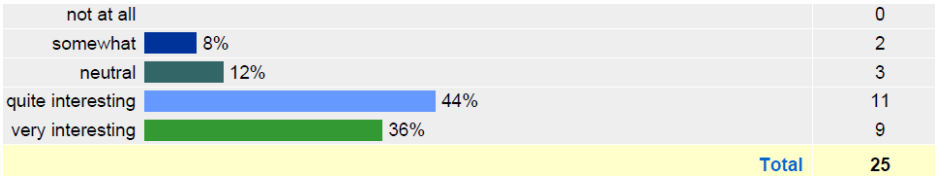


Figure 23: CAB F3 response to survey question related to how interesting the CDS concept was to the respondents. n=25

The respondents supported a CDS type solution in their monitor improvement needs wish-list. CDS specific solutions were relayed; the clinicians stated that they would like to see "*parameter fusion for clinical decision support*"[10], and "*a sensible interpretation of data*"[11] which is presented in a customizable way. The glut of information presently available was also discussed, in that "*clinicians are faced with a wide variety of information on a daily basis*…and …*they lack a very strategic method to shift through all of the data and make faster/informed decisions*"[12]. Decreasing the amount of alarms and improved data continuity were also mentioned frequently.

The responses to the survey's other questions can be grouped by theme. The themes are as follows:

- Usefulness and utility of the CDS
- Professional boundaries and touch points during CDS use
- User requirements for CDS

[9] Respondent 16, CAB F3
[10] Respondent 4, CAB F3
[11] Respondent 16, CAB F3
[12] Respondent 23, CAB F3

- Application of CDS

These themes are discussed in the following sections.

8.5.4 Results CAB F3 Theme 2: CDS Usefulness and utility

The respondents were asked two questions related to CDS usefulness and utility. They were asked to assess how CDS would be useful for them in a clinical situation. In a separate question, they were asked how they would utilize CDS. The fields allowed for free-text, and the respondents were encouraged to describe, for example, patient cases and types of information they feel CDS would be useful for. This in turn is used to reflect on the requirements but also to determine if there are any unique concepts which could be evaluated further, and outside of this research. The participants were also asked how they would use the CDS if it were available. This was an open-ended question, and it allowed for imagination and the ability to innovate for a future use.

The responses were analyzed and organized into two major categories in terms of usefulness and utility, both parts of usability. The CDS would be used in a clinical context as a(n):

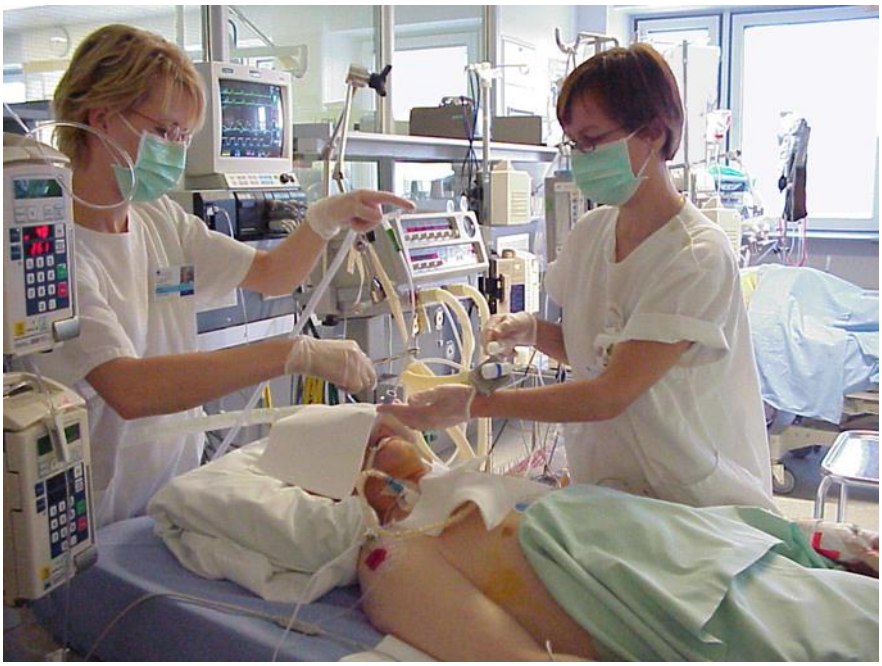
- Alerting watchdog (usefulness)
    - early warnings or positive outcome identification (= change in patient state)
    - safety net
- Guiding assistant (utility)
    - to provide for improved assessment
    - predictive value to a patient health state change

These results will be discussed in the next sections.

The CDS was viewed by many to be an alerting watchdog, an extra pair of eyes or a safety net. Especially the nurse respondents saw CDS as a savior, as it would be a method to "*prevent disasters*"[13], assure and support that changes are not being missed, give the ability to "*have more eyes on the patient, making sure that I'm not overlooking some subtle change*"[14], and support the nurse to notice physiological changes. Many viewed the CDS as a method of alerting in relation to potential adverse events or for optimizing timing for physician contact. CDS would assist, especially the

[13] Respondent 1, CAB F3
[14] Respondent 15, CAB F3

bedside clinicians, to see "*the complete picture sooner - and more importantly to be able to react earlier to the possible crisis*"[15]. All of these uses enhance the effective clinical workflow of the practitioners.



Picture 2: Nurses are providing respiratory interventional care in the ICU. The patient monitor is on the shelf, displaying real-time waveforms and digits. Picture: company files.

Some of the respondents saw CDS as potentially becoming a safety factor to counteract the global nursing shortage. The nursing shortage is seen in understaffing and less experienced staff. Concerns included medical and surgical unit staff who were deemed to be "*newer, over worked, and have sicker patients. Especially third shift when they need more help with less staff*"[16]. The relevance of CDS solution was highlighted by a nurse from the Australia/New Zealand region; with the nursing shortage, nurses are becoming scarce. "*Effectively you are having less (sic) nurses (*to*) look after more patients, with less experienced persons looking after more critically ill patients. CDS would create a safety net for clinicians and help empower them to make better decisions faster with more substance."*[17] One rather worrisome response for CDS use was in the case of a critically ill patient; the respondent said CDS would be

[15] Respondent 24, CAB F3
[16] Respondent 1, CAB F3
[17] Respondent 13, CAB F3

useful "*when you are not sure what is wrong, but you try to treat them in spite of that*."[18] The clinicians would be provided with a safety net in terms of the CDS. It would be a back-up for them during their shift, potentially saving them and their patient from a situation that could have an adverse effect. The CDS would provide an ever-vigilant processing of the life functions of the patient.

In terms of guiding care, clinicians gave examples how CDS would stretch and improve their clinical viewpoint. CDS would assist in producing a positive patient outcome, or to increase knowledge about the patient's reaction to nursing interventions. The nurses would use the CDS as an adjunct to interventions they perform. The CDS would be a tool for enhanced assessment, providing an arial view of the acquired data, giving a helicopter view of the patient before, during, and after care interventions. One of the nurses summarized, "*we know as clinicians that the early* (sic) *you treat a patient the better the outcome. Clinicians today respond to data as or after the event is occurring. We need to assist them to see a trend well in advance of a decline."*[19] It can be determined that the nurses would utilize CDS as an intuitive tool.

The CDS was seen as an aid to view "*the complete picture sooner and more importantly to be able to react*"[20]. As one nurse stated, she would use CDS to "*follow how interactions develop and use it as feedback for the actions I have performed- how effective is my treatment - is it going to the correct direction?"*[21] Another mirrored this thought and added a reflective cause/effect relationship; she would be provided with "*useful and relevant information in critical patient cases for better decision making*."[22] This added, arial assessment view provided by the CDS would be used by nurses for the following care-related times:

- before the care intervention (assess for patient readiness/stability),
- during the intervention (assess patient tolerance to the procedure) and
- after the intervention (assess patient recovery and return to physiological baseline state).

CDS was seen as a supportive tool to the operative framework of nursing bedside practice.

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[18] Respondent 14, CAB F3
[19] Respondent 13, CAB F3
[20] Respondent 24, CAB F3
[21] Respondent 24, CAB F3
[22] Respondent 21, CAB F3

One of the nurses stated, "*CDS helps (with customizable selection of protocol parameters, fusion of parameters/clinical data) clinicians (even novice) in care unit to monitor the patient more comprehensively than just by traditional 'raw data of ECG, SpO2, NIBP, Resp Rate, CO2...separately*"[23]. Another nurse believed that a patient-case tailored CDS could be designed "*to meet regional or user protocols (and it) will provide much more intelligent info. This would allow critical decisions to be made faster."*[24] Yet another nurse summarized CDS as an assistive aid which would also increase quality in patient care by automating the actual clinical thought processes:

> *The amount of information that we get per patient now is huge and it is very easy to overlook some parameter or information that actually would make you change the treatment or medication. Since humans cannot process all the information, but computers can, why not create "templates" for specific situations, diseases etc. that could give suggestions to clinicians. Eg. patient is at risk of getting certain post-op complication and when group of parameters is moving to bad direction, a notification is given to the clinician "have you considered that patient is in risk of".* (sic)
>
> – Respondent 15, CAB F3 (nurse)

Her vision supported a CDS type application serving as a guiding watchdog.

8.5.5 Results CAB F3 Theme 3: Use boundaries and touch points

Professional usage boundaries

The respondents believed that nurses and physicians would use the CDS differently; 84% (n=21) held this opinion (Figure 24). The respondents felt that CDS would be used differently by physicians and nurses in all geographical areas (Figure 25) and in all clinical environments (Figure 26); this was an interesting finding.

Figure 24: CAB F3 responses to the survey question "Do you feel physicians and nurses would use the CDS differently?" n=25.

[23] Respondent 4, CAB F3, note: parenthesis by respondent
[24] Respondent 6, CAB F3

Do you feel physicians and nurses use CDS differently?	Yes	No	**Total**
North America	8 **(100)%**	0 **(0)%**	**8**
Europe	4 **(80)%**	1 **(20)%**	**5**
Asia	2 **(100)%**	0 **(0)%**	**2**
Australia/ New Zealand	7 **(88)%**	1 **(12)%**	**8**
n	21	2	**23**

Figure 25: CAB F3 responses to survey question cross referencing geographic location to "Do you feel physicians and nurses would use the CDS differently?" Responses n=23.

In raw data analysis, it was clear that the zero-weighted responses "other" n=2 (8%) were generally indicating that CDS would be used differently by different professional groups.

All respondents wrote in the comments section.

Clinical specialty	**Do you feel physicians and nurses would use the CDS differently?**		
	Yes	No	**Total**
Anesthesia (includes all areas, adult)	7 **(88)%**	1 **(12)%**	**8**
Anesthesia (includes all areas, pediatrics)	5 **(100)%**	0 **(0)%**	**5**
Cardiac ICU	8 **(89)%**	1 **(11)%**	**9**
ICU	11 **(85)%**	2 **(15)%**	**13**
ER /Trauma	13 **(100)%**	0 **(0)%**	**13**
PICU	1 **(100)%**	0 **(0)%**	**1**
NICU	3 **(100)%**	0 **(0)%**	**3**
Medical / Surgical	8 **(100)%**	0 **(0)%**	**8**
OB GYN/ L&D	0 **(0)%**	0 **(0)%**	**0**
Transport/flight	2 **(100)%**	0 **(0)%**	**2**
Step-down	2 **(100)%**	0 **(0)%**	**2**
Neurology	1 **(100)%**	0 **(0)%**	**1**
n	61	4	**65**

Figure 26: CAB F3 responses to survey question cross referencing multiple choice response for clinical specialty to "Do you feel physicians and nurses would use the CDS differently?" Responses rounded. n=65.

Many nurse respondents claimed that, as the focus of the profession is different: physicians concentrate on medical diagnosis and treatment versus nurses focusing on direct care and intervention outcome practices. It was felt that the nurses would use the CDS "*probably more for deciding immediate/adequacy of intervention*"[25], and

> *especially nurses would use CDS as it would provide them additional important data for their* (decision) *making. The CDS data would be especially useful for example during night* (shift) *when doctors are not all the time present* (sic).
>
> - Respondent 21, CAB F3 (nurse)

It was also pointed out that

> *doctors are not at the bedside or with the patient 24 hours a day, nurses are. Nurses are the ones that need to detect the subtle changes faster to alert physicians. Physicians want to be spoon fed information and (typically) do not have the time to dive into multiple pages of information. Something gets missed.*
>
> - Respondent 23, CAB F3 (nurse)

CDS was also seen by the nurses as a nursing empowerment tool. This was interesting, in that the word empowerment came up many times in the free text, but was neither mentioned during the PowerPoint presentation nor otherwise. However, the "liberation" of nurses was seen as an additional factor CDS would provide. "*Nurses would use this as a guideline for empowerment…*(to) *see a patient who is outside the parameters set as safe in hospitals to catch the deteriorating patient"*[26].

One physician stated that the difference in CDS use lies in the care practice focus area, "*nurses would likely use it to closely monitor on a minute to minute basis to "steer the ship". Physicians should be looking* (at trends) *to set the course parameters*."[27] One of the advanced practice nurses with a degree in nursing education felt that "*physicians* (will use) *CDS data for analysis, interpretation, decision making on how to customize* (and) *optimize the CDS tool used* (and) *further course of action. Nurses will use this for quality* (and) *timely care, by applying rules*."[28] Another hypothesized that "*medical staff would use CDS in more depth and more* (regularly) *to guide patient treatment whereas nurses would use it for information/education*."[29] The few

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[25] Respondent 7, CAB F3
[26] Respondent 13, CAB F3
[27] Respondent 10, CAB F3
[28] Respondent 16, CAB F3
[29] Respondent 12, CAB F3

disagreeing answers were supported as "*I think it depends more on personal way to work than education*"[30] , or "*in the care areas concerned there is* (a) *general systematic assessment of patients"*[31]*.* Clearly, the professional focus, situational awareness, and professional boundaries are realized, and perhaps stereotypically between the two professional camps.

Moreover, physical location of the care provider was seen as a determining factor for the use of CDS. Nurses stated they were at the bedside or in direct contact with their patients 24/7, while the physicians provided episodic care, even distance care during nights or on-call periods. *"Doctors would probably look the detailed information more often when visiting patient*"[32], making the use situational. The nurses' statements related to their vigilant omnipresence could have lowered their perceived need to utilize CDS. As the nurses were present with the patient, they rationalized they knew how the patient was doing without consulting a CDS. Some of the nurses stated that they may not even need to use the CDS at all.

It can be determined from this information that during a monitoring situation, the nurses and respiratory therapists would most likely use the CDS differently from physicians. These differences in use are due to differences in professional focus (cure vs. care) and boundaries (limitation of practice), as well as differences in situational awareness (time and state) related to the patient at time of contact.

One expected response was not reported by any of the respondents. The respondents did not state that CDS could be used as a shift transfer report aide in reviewing patient state. This finding was surprising, as the helicopter view of the patient was limited to procedural interventions, not for the status follow-up over a longer period of time.

Touch points

The respondents were asked to estimate the frequency with which they would use CDS, estimating their touch points with the application. This is a theoretical question, as the application has not been tested or used by those surveyed. This would be a response to reflect their interest in the CDS solution and how they felt it would be

[30] Respondent 14, CAB F3
[31] Respondent 19, CAB F3
[32] Respondent 24, CAB F3

applicable to them in their working environment. One would expect the responses to mirror responses to the question related to how interesting the CDS concept was (Figure 23). In relation to frequency of use, none of the participants responded “never”; all participants reported that they would use the CDS to some extent (Figure 27). This mirrored the level of interest responses and was an expected answer.

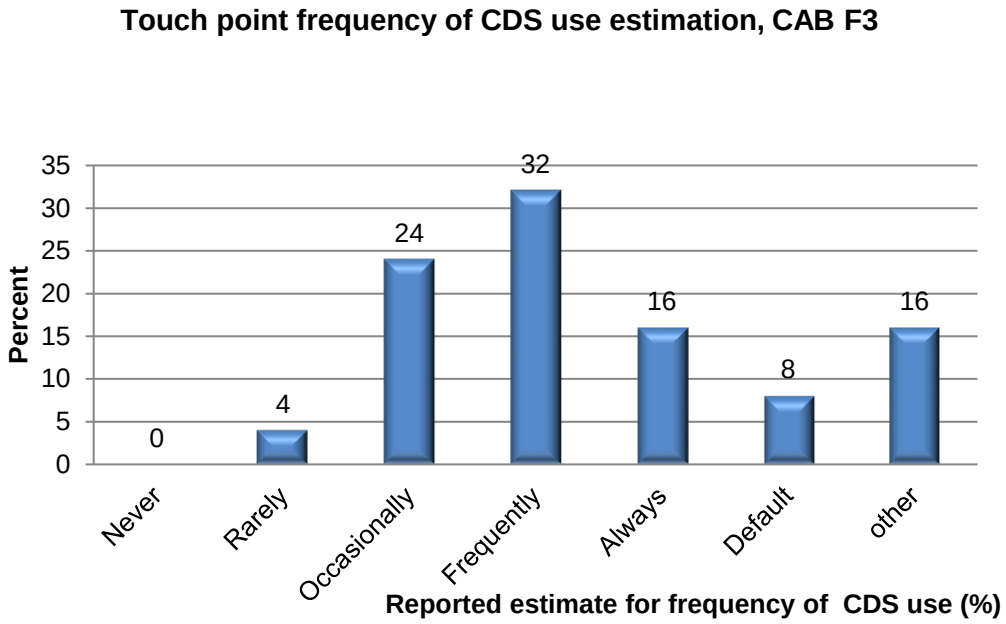


Figure 27: Frequency of use estimation of a CDS solution by CAB F3 participants, n=25.

Definitions for touch point frequency:

- ***Never***
- ***Rarely (not every patient, maybe not even daily)***
- ***Occasionally (maybe daily, at least a few times a week, some patients)***
- ***Frequently (at least a few times per shift, most or all patients)***
- ***Always (daily, all patients)***
- ***Default: I would want it as the primary default view for all of the patients***
- ***Other (free form answer)***

The majority (32%, n=8) of CAB F3 would use the CDS solution “frequently”, defined assuming CDS at least a few times per shift on most or all of their patients. The next highest amount of usage frequency was that the CDS would be used “occasionally” (24%, n=6), meaning CDS usage at least once a shift, at least a few times a week, and with some patients. Adding these two scores together, we see that over half of the respondents, 56% (n=14), would use CDS on at least a daily basis. ”Other” responses

(n=4, 16%) were examined from the raw data, and were also reflective of the positive results, in that after a learning curve, CDS was estimated to be used either always or as a default view.

Frequency of CDS use estimation	Anesthesia (includes all areas, adult)	Anesthesia (includes all areas, pediatrics)	Cardiac ICU	ICU	ER /Trauma	PICU	NICU	Medical / Surgical	OB GYN/ L&D	Transport/flight	Step-down	Neurology	**Total**
Never	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	**0**
Rarely	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	1 **(100) %**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	**1**
Occasionally	3 **(23) %**	1 **(8) %**	2 **15) %**	5 **(39) %**	1 **(8) %**	0 **(0)** %	0 **(0)** %	1 **(8) %**	0 **(0)** %	0 **(0)** %	0 **(0)** %	0 **(0) %**	**13**
Frequently	4 **(13)%**	4 **(13)%**	3 **(10)** %	4 **(13)%**	5 **(17)%**	1 **(3)%**	2 **(7)%**	3 **(10)** %	1 **(3)%**	1 **(3)%**	1 **(3)%**	1 **(3)%**	**30**
Always	0 **(0)** %	0 **(0)** %	2 **(18)%**	3 **(27)%**	4 **(36)%**	0 **(0)** %	0 **(0)** %	2 **(18)%**	0 **(0)** %	0 **(0)** %	0 **(0)** %	0 **(0)%**	**11**
Primary default view for all of the patients	0 **(0)%**	0 **(0)%**	1 **(50)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	1 **(50)%**	0 **(0)%**	**2**
n	7	5	8	12	10	1	3	6	1	1	2	1	**57**

Figure 28: Frequency of CDS use estimation by CAB F3 clinicians cross-tabulated with clinical area (rounded).

These results were cross-tabulated with the preference and clinical usage area, also producing a use frequency of “frequently” per care area (Figure 28). What was interesting in the cross-tabulation was that a respondent, determined to be a NICU nurse through raw data assessment, stated that she would use the feature “rarely”. Oxycardiorespirogram (OCRG) is, by its definition, a neonatal CDS application. This finding is supported in that not all NICU patients present with apnea, the main reason to utilize the OCRG. All other care areas would utilize CDS at least occasionally.

Default view (= shown all of the time) preferences of CDS were analyzed. The “primary default preference” responses (n=2) were from European nurses with 10 – 15 years of

experience and worked in step down and cardiac ICU units. The two respondents who want CDS as defaults on their monitoring screen both come from clinical scenarios which have less total monitoring than medical ICUs. Through raw data analysis, it was noted that both respondents reported missing subtle changes as a concern. CDS, in this case, would act as a watchdog.

Frequency of CDS use vs region	North America	Europe	Asia	Australia/ New Zealand	**Total**
Never	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	**0**
Rarely (not every patient, maybe not even daily)	1 **(100)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	**1**
Occasionally (maybe daily, at least a few times a week, some patients)	0 **(0)%**	2 **(33)%**	1 **(17)%**	3 **(50)%**	**6**
Frequently (at least a few times per shift, most or all patients)	4 **(50)%**	0 **(0)%**	0 **(0)%**	4 **(50)%**	**8**
Always (daily, all patients)	2 **(50)%**	0 **(0)%**	1 **(25)%**	1 **(25)%**	**4**
I would want it as the primary default view for all of the patients	0 **(0)%**	2 **(100)%**	0 **(0)%**	0 **(0)%**	**2**
n	7	4	2	8	**21**

Figure 29: CAB F3 respondents CDS use estimation by region (rounded). n=21. There were four zero-weight responses. Zero weight responses included more information in the free-text field, and indicated use would be related to clinical site.

The use scenario was examined by geographical location and the earlier “frequently” and “occasionally” response (Figure 29) was reflected here. European respondents had the largest disparity, in that half would use CDS as a default (shown all of the time) view, while half would use it occasionally. The North American neonatal unit user was the only “rarely” respondent. Again, no matter what the geographical location was, a majority of the users predicted they would use the CDS “occasionally” to “frequently”. CDS solutions could expect clinical acceptance in a global forum.

8.5.6 Results CAB F3 Theme 4: User requirements

The CDS user requirements were not known. To determine the user requirements, the survey participants were asked to rate basic requirements using Likert-like scales. The lowest rank for a potential requirement was “not needed at all”, with the highest rank being “critical requirement”. As a critical requirement, the feature would be also

deemed to be in a Critical to Quality (CTQ) state. These are features that are a must for the user and will eventually be ranked, tested and measured for validity.

For a feature (=requirement) to be deemed as desirable, the rating should be of “high importance” or “critical requirement”. A critical requirement is something the design must have. If something is rated as “high importance”, it is also seen as a potential requirement. Therefore, the columns “high importance” and “critical requirement” can be examined as a cumulative response. It is easily seen that the entire chart slants towards the high importance and critical requirement columns for questions, and the cumulative of the high importance and critical requirements are combined in the cumulative percent column. It was determined that a cumulative score of 75% or higher would rate the requirement as a CTQ user requirement. The results for potential CDS requirements are presented in Chart 7.

ID	All Potential CDS Features	Requirement ranking					Cumulative *n* and (cumulitive %)	Cumulative % (High + Critical)
		Not needed at all	Low importance	Moderate importance	High importance	Critical requirement		
1	Improve trend visualization	0 (0%)	1 (4%)	2 (8%)	17 (68%)	5 (20%)	25 (100%)	88%
2	Utilize calculated parameters (for example cc, pc, etc)	1 (4%)	2 (8%)	5 (20%)	16 (64%)	1 (4%)	25 (100%)	68%
3	Show interrelationships between parameters (= ”stacking")	0 (0%)	2 (8%)	5 (20%)	12 (48%)	6 (24%)	25 (100%)	72%
4	Customizable layout	1 (4%)	0 (0%)	7 (28%)	9 (36%)	8 (32%)	25 (100%)	68%
5	Customizable parameter list	1 (4%)	1 (4%)	2 (8%)	12 (48%)	9 (36%)	25 (100%)	84%

ID	All Potential CDS Features	Requirement ranking					Cumulative *n* and (cumulitive %)	Cumulative % (High + Critical)
		Not needed at all	Low importance	Moderate importance	High importance	Critical requirement		
6	Customizable amount of screen used for trends vs real time	1 (4%)	0 (0%)	9 (36%)	9 (36%)	6 (24%)	25 (100%)	60%
7	Availability of pre-configured templates/ protocols (sepsis view, stroke view respiratory view etc.)	1 (4%)	3 (12%)	6 (24%)	13 (52%)	2 (8%)	25 (100%)	60%
8	Ability to adjust trend data display [33]	0 (0%)	1 (4%)	7 (28%)	15 (60%)	2 (8%)	25 (100%)	68%
9	Ability to view CDS to a mobile device	1 (4%)	3 (12%)	5 (20%)	8 (32%)	8 (32%)	25 (100%)	64%
10	Ability to view CDS to a central station	0 (0%)	2 (8%)	4 (16%)	10 (40%)	9 (36%)	25 (100%)	76%

Chart 7: Results for potential CDS requirements by CAB F3. n=25

The **top three CTQ user requirements** are those requirements with a measured cumulative percent of 75% or over. From this set of proposed requirement features, the CTQ requirements are listed in descending priority order, as follows:

- the need for an improvement in trend visualization (88%),
- a customizable parameter list (84%), and
- the ability to view CDS from a central station [34] (76%).

These numbers are also similar to the stated need for a change in the monitor with the favorability of the CDS concept. The highest priority item, the need for an improvement in trend visualization, is support for the CDS level II concept as a whole. These two

[33] percent of screen or retrospective time shown concurrently with real time data
[34] a workspace at a location other than the bedside where may patient's data can be viewed simultaneously without the need to be in contact with the patient or the patient's monitor

usability and utility categories listed earlier were also in line with CTQ requirements. It can therefore be concluded that the CTQs are accurate.

These CTQs are relevant in terms of clinical practice. The ability to customize the parameter list for the CDS application would personalize the CDS for the clinician and tailor the needs for the patient. The clinician could configure what parameter sets are to be examined in a tailored and relevant way, therefore providing their own solution to fit a clinical need. The ability to view the CDS application from, for example, a nursing station based central station would give the clinicians the ability to freely collaborate with other clinical peers related to the state of the patient. It could potentially provide for an unseen need: an efficient shift change. The customization, here too, could allow for a quick change in viewing options, combining the parameter sets in various ways for more information and potential validation of clinical pathway. This analysis is further supported by the free text from clinician responses.

As all of the requirements were not CTQ requirements (over 75% of the votes), the remaining requirements were analyzed to determine their relevance as a user requirement. The cumulative percent of "moderate" and "high importance" requirements were examined in cases where the cumulative percent of "high" and "critical importance" were between 60% and 75%. This analysis was performed to compare and determine if the said potential requirement was of user requirement level, or if it could be graded as an optional or "nice to have" feature. The comparison of these cases is presented in Chart 8.

Remaining potential CDS feature ranking

ID	Remaining Potential CDS Feature	Totals of select responses			Comparison of cumulative %s and analysis		
		Moder-ate impor-tance	High impor-tance	Critical require-ment	Cumulative % Moderate + High	Cumulative % High + Critical	Analysis of the stated requirement
2	Utilize calculated parameters (for example cc, pc, etc)	5 (20%)	16 (64%)	1 (4%)	84%	68%	Moderate UR, not a CTQ
3	Show inter-relationships between parameters (= "stacking")	5 (20%)	12 (48%)	6 (24%)	68%	72%	UR feature, not a CTQ
4	Customi-zable layout	7 (28%)	9 (36%)	8 (32%)	64%	58%	Moderate UR, not a CTQ

ID	Remaining Potential CDS Feature	Totals of select responses			Comparison of cumulative %s and analysis		
		Moder-ate impor-tance	High impor-tance	Critical require-ment	Cumulative % Moderate + High	Cumulative % High + Critical	Analysis of the stated requirement
6	Customi-zable amount of screen used for trends vs real time	9 (36%)	9 (36%)	6 (24%)	72%	60%	Moderate UR, not a CTQ
7	Availability of pre-configured templates/ protocols (sepsis view, stroke view respiratory view etc.)	6 (24%)	13 (52%)	2 (8%)	76%	60%	Moderate UR, not a CTQ
8	Ability to adjust trend data display [35]	7 (28%)	15 (60%)	2 (8%)	88%	68%	Moderate UR, not a CTQ
9	Ability to view CDS to a mobile device	5 (20%)	8 (32%)	8 (32%)	52%	64%	UR for CDS, not a CTQ

Chart 8: The remaining potential user requirements are ranked for non-CTQ User requirement (UR) for CDS or potential UR (Moderate user requirement) status. The comparison is made by determining cumulative scores for user ranked Moderate Importance + High Importance and High Importance + Critical requirement. CAB F3 results.

According to this break-down analysis, the **needed user requirements in addition to the CTQ requirements** discussed previously are in descending priority order of high and critical scores as follows:

- Show interrelationships between parameters (= ”stacking"), 72%
- Ability to view CDS to a mobile device, 64%

The remainder of the potential CDS **user requirements** are **ranked as moderate, non-CTQ** and listed as follows, in descending priority order of cumulative moderate and high scores:

- Ability to adjust trend data display (percent of screen or retrospective time) shown concurrently with real time data, 88%

[35] percent of screen or retrospective time shown concurrently with real time data

- Utilize calculated parameters (for example cc, pc, etc.), 84%
- Availability of pre-configured templates/protocols (sepsis view, stroke view, respiratory view, etc.), 76%
- Customizable layout, 74%
- Customizable amount of screen used for trends vs real time, 72%

These moderate, non-CTQ items could also be considered, in reverse order, for elimination from the concept as user requirements. They could be product requirements linked to actual user requirements. However, given the high ranking of the features in general, all can be considered to be clinician determined user needs, with varying level of priority. The other requirements can also be deemed to be valid, as they all scored relatively highly in the survey. It can be suggested that all of the items be included in user requirements in some form.

8.5.7 Results CAB F3 Theme 5: Application of CDS

In order to be usable, the solution has to meet the interface needs of the user. The clinicians stated that they would like to have parameters presented in an interrelated way. One of the respondents said, "*items are less straightforward to diagnose and may benefit from decision support algorithms*."[36] Figure 30 shows the E-series modules available during multi-parameter monitoring with a company patient monitor. From these available parameters, the clinician should be able to build a set of appropriate values for CDS.

The clinicians were asked about the views they would prefer during CDS assisted monitoring. Some of the views were current outcome states (for example stroke, sepsis), and some were care-related status assessments (neurological, oxygenation status, etc.). All views were listed together, as one of the premises of CDS is that it will assist in the prediction of pending health events and therefore allow for early intervention and perhaps negation of said adverse events (Slide 29 in Appendix 1).

[36] Respondent 7, CAB F3

Measurement parameter module, E-series modules															
Name of series module or algorithm	Temperature	Non-invasive blood pressure	Invasive blood pressure	Surgical Pleth Index	ECG	SpO2	Neuromuscular transmission	Cardiac output	Continuous cardiac output	SvO2	EEG	BIS	Entropy	Respiratory rate	Pulse rate
NMT							X								
COP	(X)	X						X							(X)
COPSv	(X)	X						X		X					(X)
PiCCO	(X)	X							X						(X)
EEG											X				
PRESTN	X	X	X		X	X								X	(X)
RESTN	X				X	X								X	(X)
BIS												X 1)			
En-tropy													X		
PP			XX												(XX)
PT	X		X												(X)
SPI				X											
Nellcor SPO_2						X 1)									(X)
Masi-mo SPO_2						X 1)									(X)
EK Pro					X										

Figure 30: Module series and algorithm parameter portfolio (researcher). Note that all of the parameters are not listed here, just the general measurement principle of the monitor. For instance, PiCCO option has over twenty parameters to choose from.

1) Denotes that these are external provider parameters. (X) Denotes that the parameter is present either once (X) or twice (XX).

Application preferences

Based on the premise of tailored CDS views per health state, the clinicians were asked to pick as many default clinical situations from nine predetermined applications, and as free-text "other" they would want to apply CDS to. Free text for "other" was used in a limited fashion. Although the choice "other" was ticked, the open form fields held very little information of other proposed applications. The clinicians chose 153 applications during open voting. With the open voting, the top applications were cardiac events (21 votes), sepsis (20 votes), and hemodynamic status (20 votes). Other applications such as stroke (19 votes) and neurological status (18 votes) were close contenders.

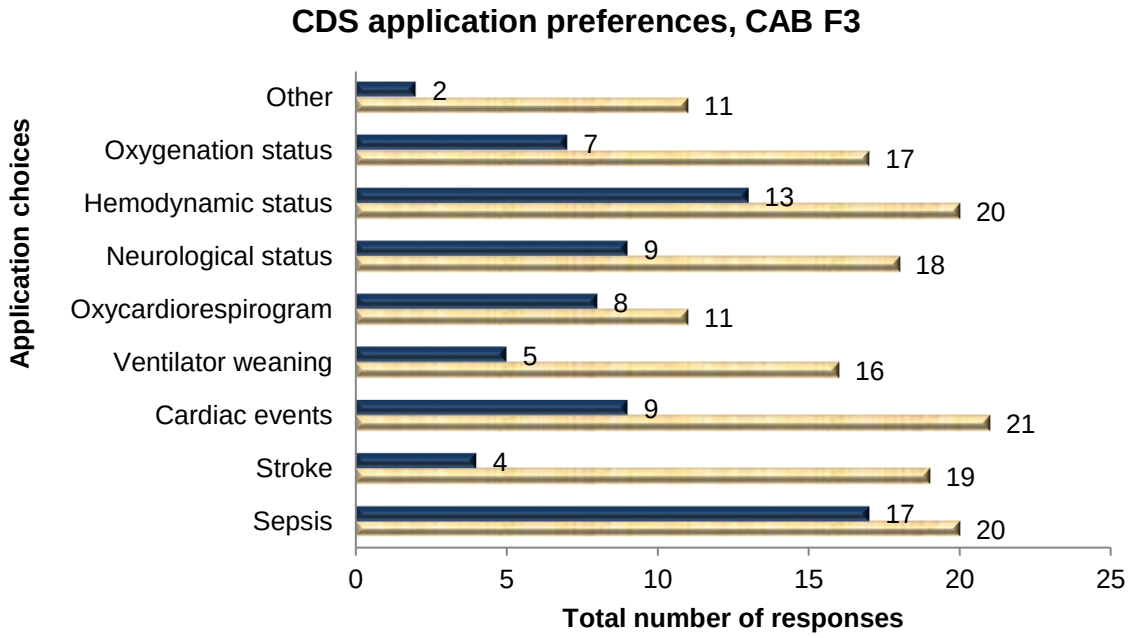


Figure 31: Application preferences during open voting and narrowed voting, CAB F3. n= 25;

Legend:
Gold column = open voting (OV)
Blue column = narrowed voting (NV)

The clinicians were then asked to reappraise the same predetermined application list and pick only their top three application preferences. This would narrow the amount of responses by over one-half (maximum 3 x 25, n_{max}=75) and cause the respondents to weigh their answers. There were a total of 74 votes. In this round of voting, the responses were slightly different; although the top votes went to sepsis (17 votes), hemodynamic status (13 votes) and a tie for neurological status and cardiac events (each at nine votes), the next contenders had changed. OCRG, a NICU application, had bounded up (8 votes) and oxygenation status followed closely behind (7 votes).

Round one open voting's choice of stroke had lost its foothold. Figure 31 presents a comparison of the total responses during open voting and narrowed voting.

As some of the changes were dramatically different, the percentage of retained votes per application area was assessed, thus determining which applications had retained loyalty. This retained percent (RP=NV/ OV) was then ranked from highest retained percent of votes to the lowest in order to produce a rank in the retained percent (RP_R). Finally, to assess the total ranking, open voting scores, narrowed voting scores and rank in retained percent were added together to produce a cumulative ranking score (CRS_R). The application area's Cumulative Ranking Score (CRS, calculated $OV_R + NV_R + RP_R = CRS$) takes into account all of the voting ranks plus the ranking of the retained percent. This attempts to give a full picture of the votes and to give each vote some weight regardless of the voting round to the vote was placed. In this way, no data is lost or unused. The results of the CSR were then ranked, producing the CSR_R. The lower the CSR_R, the more attractive and favorable an option is.

CDS Application area preferences	**Rank in open voting (OV_R)**	**Rank after narrowed voting (NV_R)**	**Retained percent (RP= NV/ OV)** ***label %***	**Rank in retained percent (RP_R)**	**Cumul-ative ranking score (CRS= OV_R+NV_R +RP_R)**	**Ranked Cumula-tive rank score (CRS_R)**
Sepsis	2*	1	85	1	4	1
Stroke	4	8	21	8	20	7
Cardiac events	1	3*	42	5	9	3
Ventilator weaning	7	7	33	7	21	8
Oxycardio-respirogram	8*	5	72	2	15	5
Neurological status	5	3*	50	4	12	4
Hemodynamic status	2*	2	65	3	7	2
Oxygenation status	6	6	41	6	18	6
Other	8*	9	18	9	26	9

Chart 9: Ranking of CAB F3 top three preferences for potential CDS application. Final scores are in the Ranked Cumulative rank score (CRSR) column on the right. Lower CRS_R indicates greater preference.

**** Symbol indicates a tie.***

The CRS_R were then placed in ordinal ranking with the lower score being the better score. After this process, the top three applications for CDS were determined. According to the CSR_R, the top three application areas for CDS to first focus on are

sepsis, hemodynamic status, and cardiac events (Chart 9). This narrowing down of the scope will support the user requirements for customizable parameter lists, improved trend visualization, displayed interrelationships between parameters, guidance in making preconfigured templates, and in using customized layouts.

It was interesting to note that even though a minority of the respondents had a neonatal intensive care background, the neonatal application of OCRG retained high support from the respondents as a whole. This demonstrates that the respondents were looking at not just their own application area but at a pan-hospital level. The respondents looked at clinical needs in a holistic and business manner, not just tied to their own clinical specialty.

TOP THREE CDS clinical concepts	**Professional practice area (rounded)**												
	Anesthesia (includes all areas, adult)	Anesthesia (includes all areas, pediatrics)	Cardiac ICU	ICU	ER /Trauma	PICU	NICU	Medical / Surgical	OB GYN/ L&D	Transport/flight	Step-down	Neurology	**Total**
Sepsis	6 **(14)%**	2 **(5)%**	5 **(12)%**	11 **(26)%**	9 **(21)%**	0 **(0)%**	1 **(2)%**	5 **(12)%**	0 **(0)%**	1 **(2)%**	2 **(5)%**	1 **(2)%**	**43**
Stroke	1 **(10)%**	1 **(10)%**	1 **(10)%**	2 **(20)%**	3 **(30)%**	0 **(0)%**	0 **(0)%**	1 **(10)%**	0 **(0)%**	0 **(0)%**	1 **(10)%**	0 **(0)%**	**10**
Cardiac events	3 **(12.5) %**	2 **(8)%**	3 **(12.5) %**	6 **(25)%**	6 **(25)%**	0 **(0)%**	1 **(4)%**	3 **(13)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	0 **(0)%**	**24**
Ventilator weaning	2 **(12)%**	1 **(6)%**	2 **(12)%**	4 **(25)%**	2 **(12)%**	0 **(0)%**	0 **(0)%**	2 **(12)%**	0 **(0)%**	1 **(6)%**	1 **(6)%**	1 **(6)%**	**16**
Oxycardiorespiro gram	2 **(8)%**	1 **(4)%**	2 **(8)%**	4 **(16)%**	5 **(20)%**	1 **(4)%**	3 **(12)%**	3 **(12)%**	0 **(0)%**	2 **(8)%**	1 **(4)%**	1 **(4)%**	**25**
Neurological status	5 **(14)%**	3 **(9)%**	4 **(11)%**	4 **(11)%**	6 **(17)%**	1 **(3)%**	1 **(3)%**	4 **(11)%**	0 **(0)%**	2 **(6)%**	3 **(9)%**	2 **(6)%**	**35**
Hemodynamic status	5 **(11)%**	3 **(7)%**	7 **(16)%**	8 **(18)%**	9 **(21)%**	1 **(2)%**	2 **(5)%**	5 **(12)%**	0 **(0)%**	2 **(5)%**	1 **(2)%**	1 **(2)%**	**44**
Oxygenation status	2 **(12)%**	1 **(6)%**	3 **(19)%**	3 **(19)%**	2 **(12)%**	0 **(0)%**	2 **(12)%**	1 **(6)%**	1 **(6)%**	1 **(6)%**	0 **(0)%**	0 **(0)%**	**16**
Total	26	14	27	42	42	3	10	24	1	9	9	6	213

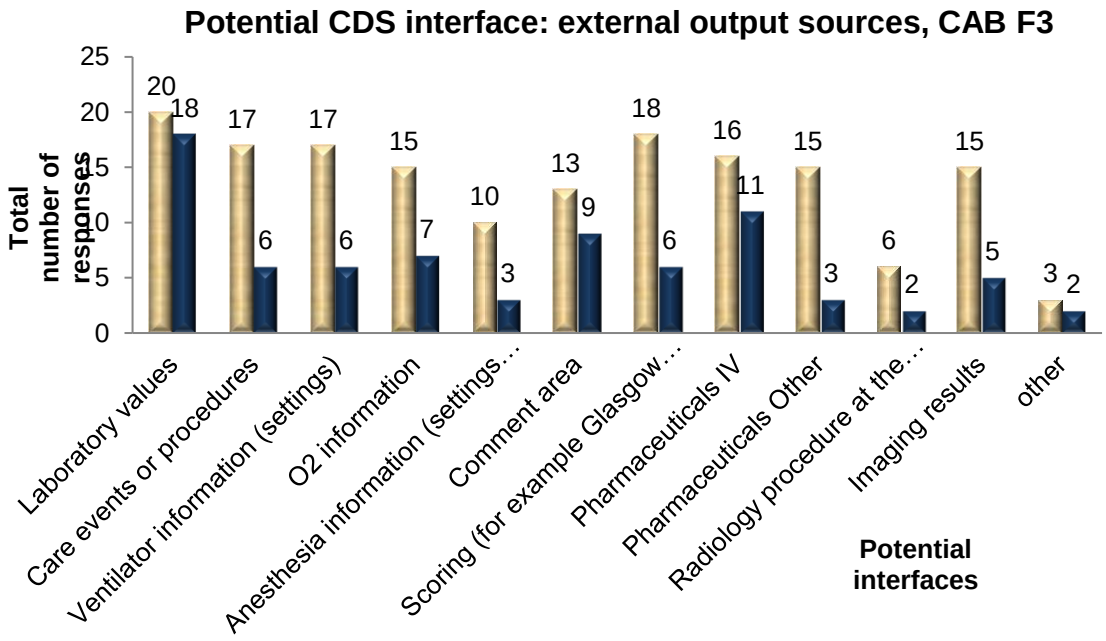
Figure 32: CAB F3 Top three CDS application preferences mapped to care area. Cross tabulation of clinical specialty to CDS concepts with each participant able to pick "top three" concepts for use.

The results were also cross-tabulated for further insight as to needs per care area specialty (Figure 32). The findings from the cross tabulation are multiple. For instance,

hemodynamics narrowly came ahead of sepsis by one vote for total votes, with neurological status ranking third. What is interesting is that per unit, the features which received higher vote counts (darker pink) reflect the patients treated on the units. The OCRG received votes from nearly every application area. Perhaps this presentation style can be implemented for other units. This information may be used during specification planning per care area. Although the sample is small, it is a clinically reasonable summation of needs. This would need further study.

Interfacing

The survey also included a question related to what non-monitoring items should be included in the CDS view. This included many items which are now either happening on a different monitor, interface, or (medical) device. Charting type items were asked, including care events or procedures, comment areas, scoring values, etc. This question was also broken down into open and narrowed voting (Figure 33).



Legend:
Gold column = open voting (OV)
Blue column = narrowed voting (NV)

Figure 33: Paired total number of votes in open and narrowed CAB F3 voting for CDS interfacing possibilities per category.

The same principles for calculating CTQ and requirement level were applied to this question of external interface preferences as were applied to CDS application area

preferences previously. Interfacing of other information would bring more data to the monitor screen, thus providing more to integrate for analysis. The results show for ranked cumulative score that interfacing laboratory values, intravenous pharmaceuticals, and oxygenation information were seen to be of most value (Chart 10). The next most important items were tied for fourth place: care events or procedures, ventilator information (settings), and a general comment area. These six items form what is commonly seen on patient charting in paper form. It is possible that the clinicians want to use the monitor as a clinical chart.

External interface preference	**Rank in open voting (OV_R)**	**Rank after narrow-ed voting (NV_R)**	**Retain-ed percent (RP= NV/ OV) *label %***	**Rank in retained percent (RP_R)**	**Cumulative ranking score (CRS= OV_R+NV_R+ RP_R)**	**Ranked Cumula-tive rank score (CRS_R)**
Laboratory values	1	1	90	1	3	1
Care events or procedures	3*	5*	35	6*	14	4*
Ventilator information (settings)	3*	5*	35	6*	14	4*
O2 information	4*	4	46	5	13	3
Anesthesia information (settings and gases)	10	9	30	11	30	10*
Comment area	9	3	69	2	14	4*
Scoring (for example Glasgow coma scale, pain scale)	2	5*	33	8	15	7
Pharmaceuticals IV	3*	2	68	3	8	2
Pharmaceuticals Other	6*	9	20	12	27	9
Radiology procedure at the bedside	11	11*	33	8	30	10*
Imaging results	6*	8	33	8	22	8
Other	12	11*	66	4	27	12

Chart 10: Ranking of CAB F3 non-monitoring items for potential monitoring interface. Lower CRS_R indicates greater preference.

**** Symbol indicates a tie***

The patient status scoring was consistent in dropping in rank, except when paired with geographical location of the respondent (Figure 34). In this case, the North Americans required scoring system(s) inclusion. This finding was interesting, as clinical evaluation scales are used in nursing practice, for example, to titrate intravenous pain medications

or to assess for level of consciousness. The intravenous medication ranked very high on the list (contributing factor to change, a cause agent), yet its need/effect (evaluation of response to cause agent) did not. Why other geographical regions did not place such importance on these rating scales is not determined.

TOP THREE non-monitoring items wanted for inclusion in a CDS view per geographical area	North America	Europe	Asia	Australia/ New Zealand	**Total**
Laboratory values	5 **(30)%**	5 **(30)%**	1 **(5)%**	6 **(35)%**	**17**
Care events or procedures	2 **(33)%**	1 **(17)%**	1 **(17)%**	2 **(33)%**	**6**
Ventilator information (settings)	3 **(50)%**	2 **(33)%**	0 **(0)%**	1 **(17)%**	**6**
O2 information	3 **(50)%**	1 **(17)%**	0 **(0)%**	2 **(33)%**	**6**
Anesthesia information (settings and gases)	0 **(0)%**	1 **(50)%**	0 **(0)%**	1 **(50)%**	**2**
Comment area	3 **(38)%**	2 **(25)%**	1 **(12)%**	2 **(25)%**	**8**
Scoring (for example Glasgow coma scale, pain scale)	4 **(80)%**	0 **(0)%**	0 **(0)%**	1 **(20)%**	**5**
Pharmaceuticals IV	3 **(30)%**	2 **(20)%**	2 **(20)%**	3 **(30)%**	**10**
Pharmaceuticals (other)	1 **(33)%**	1 **(33)%**	0 **(0)%**	1 **(33)%**	**3**
Radiology procedure at the bedside	1 **(50)%**	0 **(0)%**	1 **(50)%**	0 **(0)%**	**2**
Imaging results	2 **(40)%**	1 **(20)%**	0 **(0)%**	2 **(40)%**	**5**
Total	27	16	6	21	**70**

Figure 34: Cross-reference of interfacing top three item preference and geographical area of CAB F3.

The consistently low ranking of anesthesia information related to settings and gases was another interesting factor. At first, the relationship of this response to the amount to anesthesia practitioners was considered, but this was not deemed irrelevant as the CDS application preference had OCRG at a high preference, even though the total amount of neonatal clinicians was much lower. However, when comparing the low ranking of anesthesia information to the statement of the anesthesiologist in CAB F2, the low score is justified. Anesthesiologists use much information and incorporate it all: monitors, intravenous medication pumps, and the actual surgical event right down to the organs being manipulated. The anesthesiologist concluded that surgery is such a short-term event that trends are not needed. The anesthesia machine is an extension of the anesthesia provider; perhaps as such it is second nature to know what the status

is that extra details are not perceived as needed. It can be concluded that the low rank is a valid one, although the exact reasons remain debatable.

Care reminders

The "monitor as a chart" concept presented earlier was also supported by the large amount of clinicians who stated they would want care reminders from the monitor, reminding them of a task they were to perform. Examination of the raw data and assigning "other" responses to yes or no (n=24 plus one ambiguous response which received a zero weight count) showed that clinicians as a whole were interested in having the monitor give care reminders. These results are reported in Figure 35, with 84% (n=20) of both professions wanting a care reminder.

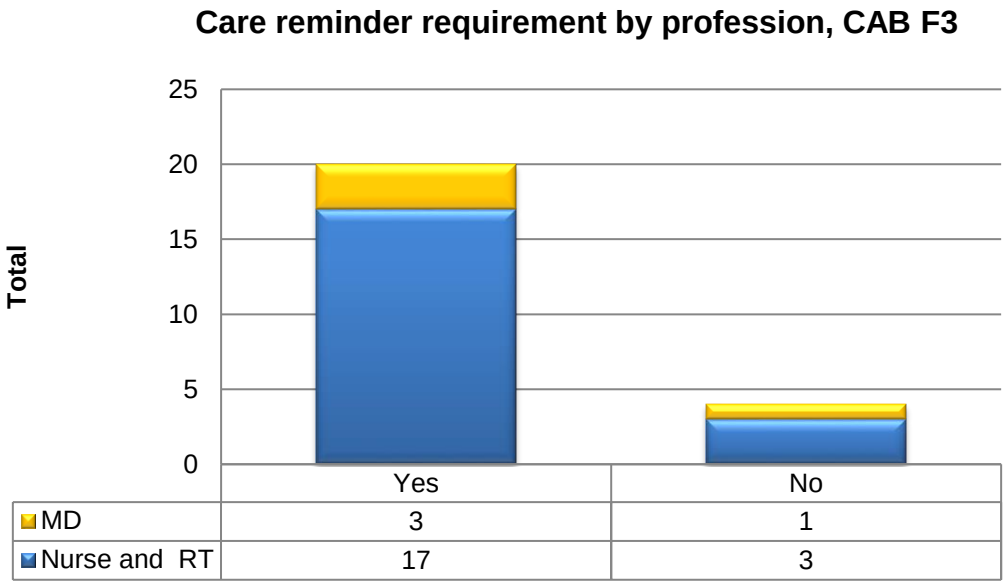


Figure 35: CAB F3 clinicians responded that they would want the patient monitor to give them care reminders.

Examining the care area requirement for care reminders (Figure 36), we find that care reminders would be a required feature in all named care areas.

What is your clinical specialty? (multiple answers allowed)	Would you want your monitor to give you care reminders?		
	Yes	No	**Total**
Anesthesia (includes all areas, adult)	6 **(86)%**	1 **(14)%**	**7**
Anesthesia (includes all areas, pediatrics)	4 **(80)%**	1 **(20)%**	**5**
Cardiac ICU	6	1	**7**

What is your clinical specialty? (multiple answers allowed)	Would you want your monitor to give you care reminders?		
	Yes	No	**Total**
	(86)%	**(14)%**	
ICU	8 **(73)%**	3 **(27)%**	**11**
ER /Trauma	9 **(90)%**	1 **(10)%**	**10**
PICU	1 **(100)%**	0 **(0)%**	**1**
NICU	3 **(75)%**	1 **(25)%**	**4**
Medical / Surgical	5 **(100)%**	0 **(0)%**	**5**
OB GYN/ L&D	1 **(100)%**	0 **(0)%**	**1**
Transport/flight	3 **(100)%**	0 **(0)%**	**3**
Step-down	3 **(100)%**	0 **(0)%**	**3**
Neurology	2 **(100)%**	0 **(0)%**	**2**
total	51	8	**59**

Figure 36: Cross-tabulation of clinical site to preference to have the monitor giving clinical reminders. n=59, showing overwhelming support for the concept in all care areas. CAB F3 results.

One nurse envisioned that the patient monitor would not only provide care reminders, but expanded on this idea and suggested that the monitor provide care protocol reminders:

> *Nurses will want more feeder data with predefined rules applied, reminders for timely delivery in care. e.g. frequency of doing blood sampling…timely administration of drugs..appropriate/right drug, dosage (medication errors), which parameters monitoring to start for a given patient condition e.g: Sepsis parameters, Fluid balance parameters, shock parameters, stroke etc, frequency of doing a report out from the CDS tools/CDS tools trending*
>
> - Respondent 16, CAB F3 (nurse)

One respondent replied to the issue of care reminders already in a previous question related to monitor improvement opportunities by saying "*customers expect the monitor to act as the collector and distributor of bedside data. They also are expecting to access hospital wide info from the bedside so the monitor becomes a portal for data*

collection and review"[37]*.* Once again, the CDS monitor would serve as a watchdog and as a guiding assistant.

Data presentation factors

When asked about what was felt was a usable and actionable CDS data presentation style, the responses could be broken into two major categories. The respondents felt that CDS should be a supportive tool with an emphasis on both visual presentation and ease of accessibility.

As to matters of presentation, both visual and graphical items were brought out by the participants as important tools for assessment. Responses were similar in terms of visual preferences; users wanted information that was presented in both graphic and numeric form, with more emphasis on graphical interfaces. Users also wanted colorful assistive support tools, "*simple traffic light style presentation with the ability to customize parameters in the set with alerts set to trigger at key points above or below*"[38] the preset limits. The overview of the monitor screen could be very general and not so "full". When needed, there would be quick access (no more than one touch) to more detailed data. Additionally, pre-selected real-time data should be shown while the CDS application is being used. For instance, if a CDS for sepsis was being used the ECG real-time waveform would be visible simultaneously. The ideal solution would be a collection of synthesized, colorful, graphical data presented so the clinician could see, at a short glance, what the patient's state is.

Many clinicians also stated that they would be interested in seeing a record of changes, deltas, in patient parameters. For instance, if the mean arterial blood pressure fluctuates, the CDS would provide information of how much change there was (delta) and at what times (scope).

> (As a clinician, I) *don't typically care if there is no change in the patients HR value (it can fluctuate by 15%), but when it starts trending I want to see quickly where they were and where they are. Seeing a Delta quickly is essential. Visualization tools of that Delta should be customizable or EASY for everyone to understand! Spider diagrams*[39] *may not be the*

[37] Respondent 6, CAB F3
[38] Respondent 6, CAB F3
[39] Spider diagram representation; various interrelated parameters are shown in a pie-shaped grid with color-coding for when the parameter is within or out of preset alarming boundaries, tracked over time. See picture 3 for an example.

> *best. IF you need to refer to a manual on what the information is trying to tell you, you missed CDS!*
>
> - Respondent 23, CAB F3 (nurse)

Simplicity and ease of use were strongly emphasized. These are all preferences that must be concept tested during design.

It was also brought up that CDS should be used as a supportive tool during nursing care. This was reflected earlier, but came through in the responses. Stressed one nurse,

> *I would like the information so that it allows me to use my nursing judgment and not diagnose a problem for me. I think in today's practice, many of the younger nurses are relying strictly on technology and not using their clinical judgment. Technology is a tool, not a practice.*
>
> - Respondent 23, CAB F3 (nurse)

This was an important observation, as CDS should not be seen or treated as a tool to eliminate the need for qualified medical and clinical personnel and their clinical judgment. This also supported the guiding assistant concept. Care in the graphical format should be made during the design. Not only does the presentation (columns, spider views, bull's eye, pie charts, etc.) need to be considered, but colors and indicative shading are of increasing importance. The theme should incorporate simplicity and intuitiveness.

Predictive analytics

Clinicians were finally asked how comfortable they would be with a CDS so advanced it could provide predictive analytics related to the patient state. An example of impending sepsis onset with the monitor advising the clinicians of the state and potential care pathways was provided. The results are presented in Figure 37 and broken down by geographical area in Figure 38.

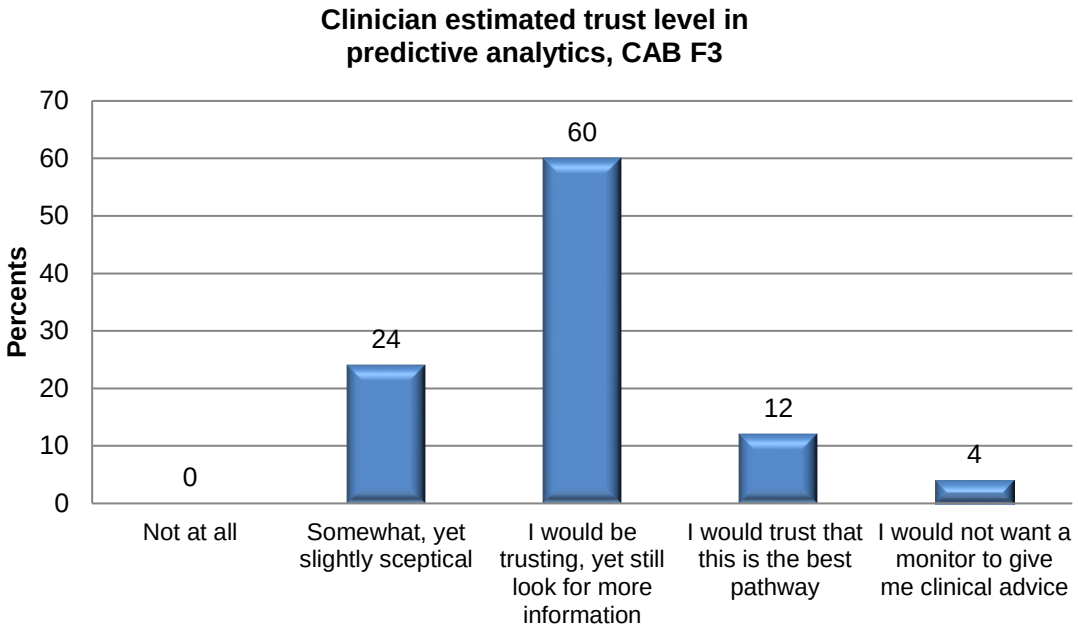


Figure 37: CAB F3 clinicians estimated trust level in monitor provided predictive analytics. n=25

From their responses, we see that the largest amount of clinicians would be trusting of the monitor, yet still seek more information. This was an expected result, as the clinicians use more than one input for providing care and treating the patients, and the novelty of assistive diagnosis has not been utilized so far. One respondent echoed the work of Balas and Soren (2000: 65-66) reported earlier, however, and predicted that acceptance for such a system will take time:

> *relying on a CDS system & algorithm will need time for the clinicians to be convinced…These tools in its infancy will be big time aids to a clinicians judgment & interpretation, as the tools/algorithms mature & set their confidence in the clinicians these tools will be perhaps one day more of a necessity than an aid!*
>
> - Respondent 16, CAB F3 (MD)

	IF CDS was so advanced it could give you predictive how comfortable would you feel with trusting the analysis?					
Geographical location	Not at all	Somewhat, yet slightly sceptical	I would be trusting, yet still look for more information	I would trust that this is the best pathway	I would not want a monitor to give me clinical advice	**Total**
North America	0 **(0)%**	1 **(11)%**	5 **(56)%**	3 **(33)%**	0 **(0)%**	**9**
Europe	0 **(0)%**	1 **(17)%**	5 **(83)%**	0 **(0)%**	0 **(0)%**	**6**

IF CDS was so advanced it could give you predictive how comfortable would you feel with trusting the analysis?						
Geographical location	Not at all	Somewhat, yet slightly sceptical	I would be trusting, yet still look for more information	I would trust that this is the best pathway	I would not want a monitor to give me clinical advice	**Total**
Asia	0 **(0)**%	0 **(0)%**	2 **(100)%**	0 **(0)%**	0 **(0)%**	**2**
Australia/ New Zealand	0 **(0)**%	4 **(50)%**	3 **(38)%**	0 **(0)%**	1 **(12)%**	**8**
	0	6	15	3	1	**25**

Figure 38: Geographical breakdown of CAB F3 predicted comfort level with acceptance of CDS suggested care pathway. The large majority of international clinicians would be moderately trusting of the monitor's care suggestions, yet still require verification via other information. n=25 (rounded figures)

Clinical assessment as a method and tool would still be used, taught, and necessary in caring for patients. The monitor would still be seen as a guide for assessment and care, along with its added value of a CDS. Combining the "somewhat, slightly sceptical" and the "trusting yet looking for more information" responses together, 84% would use the CDS as an assistive tool in patient care, yet rely on their own clinical judgment when interpreting the data. When teamed with earlier answers related to frequency of use, usability and utility, there is a consistency in the findings. This, however, would need to be studied further with the real application and in a variety of clinical settings and locations, as this was just a theoretical question.

8.6 Inductive analysis and results of the CAB F4 input

The following section is the inductive analysis of the CAB F4 survey results. Responses were divided into themes, and were analysed per theme. Direct quotations are presented in italics.

8.6.1 CAB F4 demographics

Three physicians were interviewed during CAB F4. Two of the participants were men and one was a female. They all have combined ICU and anesthesiology backgrounds in a primarily adult patient population.

8.6.2 CAB F4 focus

CAB F4 was a deep-dive into the CDS concept with three physicians. They were chosen by the KOL coordinator, once again. The KOL chose these participants, as he felt that they were opinionated and forward thinking. There had been a period of time for reflection since the last meeting on both sides. The common themes during CAB F4 included the ideal monitoring system and differences between adult anesthesia and ICU environments, and trend display preferences.

8.6.3 Results CAB F4 Theme 1: Ideal monitoring system

The focus of the discussions bridged CDS to the ideal patient monitoring system. Although the clinicians held backgrounds in both anesthesiology and intensive care, the focus was more on the anesthesia application and clinical situations which arise in that field. As the CAB F4 participants had had a period of reflection since CAB F2; they were also reflecting any changes or expansion of their previous input.

There was discussion related to CDS as a concept and some new screen views which had been made based on feedback during the design. The three clinicians were in agreement that the concept of CDS is a good one. However, it was once again pointed out that CDS cannot replace a clinician who will assess the patient state and the CDS would be an assistive tool. Care is given in part with knowledge and in part with intuition based on previous experience. As with the participants in CAB F3, this group pointed out that CDS can help identify when something is going wrong, or point out if the patient is "*poorly stable/stabiilisti huono*"[40], and adverse events evolve over time, subtly. The current state is that adverse events are reviewed on the monitor after the event has happened.

When asked if the screen view should have set combination views, for example hemodynamics or fluid balance, it was not well-received:

> *Monitoring fluid balance is very basic, fluid therapy is not based on really anything in the ICU – half related to CVP[41], half on nothing. Respiration and circulation and the global oxygenation balance is most central/ nestetasapainon monitorointi on alkeellista, nesteiden anto ei perustu minkään teholla - puolet CVP:n perusteella, puolet ei mihinkään.*

[40] Participant 1, CAB F4
[41] CVP = central venous pressure, sentraalinen venapaine

> *Hengityksen ja verenkierron ja globaalin hapenkulutuksen ja tarjonnan suhde kaikista keskeisintä. Tietojärjestelmätiedon hyödyntäminen ja kombinointi.*
>
> - Participant 3, CAB F4 (MD)

to which Participant 1 CAB F4 related the clinical issues are not black and white, and preconfigured combinations would not work.

> *Grouping doesn't work like that. The kidney: the patient does not pee, it can be circulation, fluid balance, something related to the kidney. You can't start off with an organ based index - but a basic framework. This is a basic engineering fault, thinking of it like a car – if the gear box does not work, it is broken!! The doctor cares for the pathophysiology, others care for the morphology.* (The company*) looks at it in terms of morphology!! Engineering problems have a one-way cause... / Ryhmittely ei toimi näin. Munuainen: potilaalta ei tule pissaa, voi olla verenkierto, nesteytys, munuaiseen liittyvä syy. Organ indexista voi lähteä - mutta on vain perusvalikko. Perusinsinöörivika, ajatellaan kuten autoa, jos vaihdelaatikko ei toimi, se on rikki!! Lääkäri hoitaa patofysiologiaa, muut hoitavat ilmiasua.* (Firma*) katselee ilmiasun kautta!! Insinööriongelmissa yksisuuntainen syy...*
>
> - Participant 1, CAB F4 (MD)

Co-creation was discussed, and the importance was recognized. The goal of all treatment and monitoring was named as achieving homeostasis, not in diagnosis.

8.6.4 Results CAB F4 Theme 2: Clinical setting differences

The presented information at CAB F4 was based on the acquired information from the previous CABs, especially CAB F3. There was vivid discussion when describing the differences in clinical areas and the clinical challenges for medical personnel. The differences and challenges are summarized in Chart 11, and mirror what CAB F3 results indicated.

Environment	**Situation and challenges summarized**	**In the original Finnish text**
Anesthesia (intra-operative)	*Fast and strong changes affecting physiology*	*Nopeita ja voimakkaita fysiologiaan vaikuttavia muutoksia*
	The cause is usually known -> no diagnostic problems	*Aiheuttava syy yleensä tiedossa → ei diagnostista ongelmaa*
	Problems are usually predictable	*Ongelmat yleensä ennakoitavissa*
	Surprises are rare	*Yllätykset harvinaisia*
ICU (adult focus)	*Problems are often hidden and develop slowly*	*Ongelmat usein piileviä ja hitaasti kehittyviä*
	Hard to notice	*Vaikeasti havaittavia*
	Hard to predict	*Vaikeasti ennakoitavia*
	Diagnostic prolems	*Diagnostiset ongelmat*

Environment	Situation and challenges summarized	In the original Finnish text
	The bulk of care is provided by nurses	*Hoito on sairaanhoitajapainotteinen*
	Things are continuously happening in the ICU	*Teholla tapahtuu jatkuvasti*

Chart 11: Summary of different challenges between intra-operative anesthesia and intensive care units by CAB F4 participants.

The differences between PACU and anesthesia were touched on briefly, but it was decided by the research team to probe further with a separate CAB of dedicated anesthesiologists from a global forum.

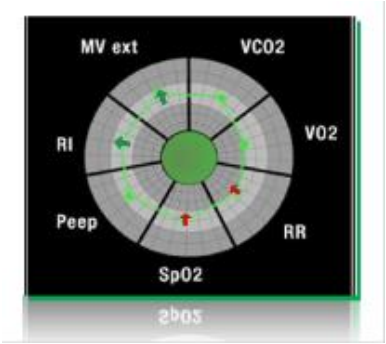
8.6.5 Results CAB F4 Theme 3: Trend display preferences

As this was a follow-up deep dive, basic ideas of screen views were not presented. However, the depth of information that the monitor would give was appraised. CAB F4 was unanimous, in that the monitor should not give diagnoses, but to

> *warn if something goes wrong. A parameter group changes in relation to one another, tell that to the clinician. You do not need to suggest a diagnosis – but clearly they want some sort of notification, not just visualized data: respiration rate increase and SpO_2 is a good example, plus the notification...Clinicians can give clear examples how the information can be combined / varoittaa, että joku menee pieleen. Joukko parametreja muuttuu suhteessa toisiinsa, kerrotaan se käyttäjälle. Ei tarvitse ehdottaa diagnoosia – selvästi kuitenkin ne haluaa jonkinnäköisen notifikaation, ei vain visualisoitua dataa, RR increase + SpO_2 decrease on hyvä esimerkki plus siihen liittyvä notifikaatio… Kliinikot voi antaa selkeitä esimerkkejä, miten tietoja yhdistellään* .
>
> - Participant 1, CAB F4

This statement led to the potential for each unit, with its clinical experts, determining its own application combinations. This would tailor the solution to the user and to the unit. In terms of presentation of the data, it was suggested that

> *an improvement in the spider view would help in the glut of information. We have to define raw alarm ranges, so that it does not alarm all of the time. Using color coding or trends, we can picture what is blinking, based on historical events…a recognizable form; that leads to or should have led to an intervention. The system should be a learning one./ hämähäkkikuvio parannus, auttaa informaatiotulvassa. Joudutaan määrittelemään karkeat hälytysrajat, jotta ei hälytä koko ajan. Värikoodein tai trendien kautta kuvataan, mikä vilkuttaa, historiallisten tapausten perusteella...Tunnistettava muoto; mikä johtaa tai olisi pitänyt johtaa interventioon. Systeemin pitäisi olla oppiva.*
>
> - Participant 3, CAB F4



Picture 3: Spider diagram example.

The presentation of data in a new way, once again, was appearing to be the key to end-user success for the application. The discussion of an intelligent monitor which is learning from the acquired data and historical data from other patients was interesting to the physicians. This would bring the monitor to a CDS Level III. Generally speaking, the clinicians wanted a

> *summary that tells you if you are within the limits or not, how much is changing and to which interventions or changes in state or diagnosis can lead to - - that is what is needed./ Yhteenveto, joka kertoo, ollaanko rajoissa vai ei, miten paljon muuttuu ja mihin interventioon tai tilanmuutokseen tai diagnoosiin voi johtaa - - sitä tarvitaan.*
>
> - Participant 3, CAB F4 (MD)

This statement supported the monitor as a chart concept which arose in CAB F3. It also supported the use of trend data during interventional care. When discussing the combination of parameters for analysis, CAB F4 Participant 3 stated that

> *the parameter analysis must combine 1) clinically significant diagnoses 2) the intervention: the ICU and the anesthesia units have clinical information system data which could be used to connect this information. / parametrikäsittelyyn pitää yhdistyä 1) kliinisesti merkittävä diagnoosi, 2) interventio: teholta ja leikkurista löytyy tietojärjestelmädataa, jota voisi hyödyntää näiden yhdistämiseen.*

It seemed that the physicians were more assured of their monitoring abilities and the need for a higher level of sophistication, in that CAB F4 Participant 1 stated that *"…physicians need more sophisticated (information). Possible conclusions can be made for the nurses,* (like telling them) if *they have to do something. / …lääkäreille sofistikoidummat (tiedot). Hoitajakin voi ehkä jo tehdä päätelmän,* (kuten kertoa) *tarviiko tehdä jotain."* This statement supports some of the views of the respondents in CAB F3, However, the level of sophistication for separate professional groups should be explored more.

8.7 Inductive analysis and results of CAB F5 input

The following section is the inductive analysis of the CAB F5 survey results. Responses were divided into themes and were analysed per theme. Direct quotations are presented in italics.

8.7.1 CAB F5 demographics

All of the respondents were in active, current practice as anesthesia physicians (n=5) at the time of focus group participation. They were KOL from North America, Europe, Asia (n=2), and Australia/ New Zealand, and were able to give global viewpoints to anesthesia care. Four were male and one was female. One participant did not participate in the survey for unknown reasons. Of the four survey participants, three had over 17 years of active practice and one had between six and ten years of active clinical practice.

8.7.2 CAB F5 general

CAB F5 was a virtual webcast event with a follow-up survey. The focus of this group was to determine not only CDS use in the anesthesia unit (ANE), but also in the PACU from strictly an anesthesiologist's viewpoint. Their views would be compared to the views of the other anesthesiology-grounded CAB participants, but the responses are only a general indication – more exploration into anesthesia and PACU are needed. This CAB was also an opportunity to show some mock-ups of CDS and receive feedback. The participants were asked how interesting the CDS concept was to them as a clinician, and the responses did show interest in the concept (Figure 39).

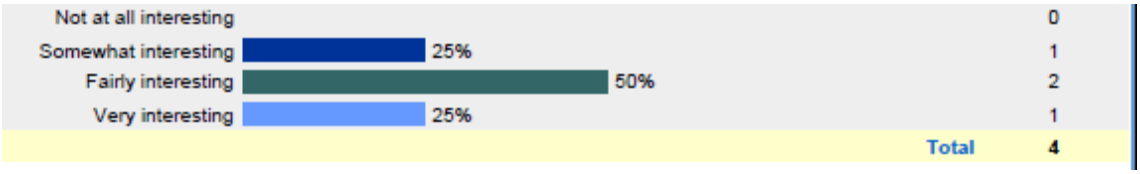


Figure 39: CAB F5 reported interest in CDS as a concept. n=4

The participants were presented CDS, and then a discussion of the topic took place. The facilitator asked open ended questions, and each participant answered each

question. The CDS concept was seen as a good one, and one worth pursuing. One participant declared, "*it is always a great pleasure to have data*."[42] The perceived clinical uses were from every day anesthesia work to teaching. The themes which were consistent in their responses were mobile applications, ease of use, and use area.

8.7.3 Results CAB F5 Theme 1: Mobile application

One proposed feature which was liked was the ability to use the CDS from a remote place via a tablet or other wireless device. One of the physicians told that a typical workday is made up of "*running between three* (operating) *rooms, a quarter of a mile back and forth*"[43]. Physicians also reported jumping back and forth between the PACU and the operating rooms. The preferred viewing method was a pad or mini-pad device. The mobile/smart phone screen was seen as too small to be practical. The mobile/smart phone may also have some regulatory issues for use in an operating environment in some Asian countries.

The younger generation ("Generation Y") of physicians was seen as more adept to and adaptive in using electronic devices and applications. Two examples of printed learning materials and standards of care being used only after being made into downloadable mobile applications were given.

8.7.4 Results CAB F5 Theme 2: CDS views and use

The respondents echoed the opinions of earlier respondents, in that the application has to be easy to access. Phrases like "*it has to be easy to get to*, *if I have to hunt for it, it'll be lost"*, and "*if people can't find it, where to make changes, they'll forget how to do it*"[44] would summarize the needs for easy, one-touch access. One participant offered a solution: "*I could imagine having three buttons 'routine', 'cardiac failure', and 'hypovolemia'. I push them, and then come the special lines and the data*"[45]. Just as in previous sessions, this group did not prefer the spider view for presentation format at all, and also stated anesthesiologists were "being harassed by alarms and

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[42] Participant 5, CAB F5
[43] Participant 4, CAB F5
[44] Participant 4, CAB F5
[45] Participant 5, CAB F5

information"[46]. The clinicians agreed that the machine currently takes up too much time alarming while they are concentrating on patient care.

To determine importance of applications for OR use, the participants were asked to rank potential applications using a Likert-like scale. The results are presented in figure 40. The applications were extracted from themes the anesthesiologists discussed during the CAB F5 presentation/discussion.

	Most important	Very important	Moderately important	Not very important	Least important	N/A	Total
Anesthesia guidance	0 (0%)	3 (75%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	**4**
Cardiac function, hemodynamics	0 (0%)	4 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**4**
Fluid status	0 (0%)	3 (75%)	1 (25%)	0 (0%)	0 (0%)	0 (0%)	**4**
Respiratory distress	0 (0%)	2 (50%)	2 (50%)	0 (0%)	0 (0%)	0 (0%)	**4**
n	0	12	4	0	0	0	**16**

Figure 40: CAB F5 anesthesiologist ranking of potential CDS applications for OR use. (n=4)

The results (Figure 40) show that cardiac function and hemodynamic receive unanimous support from all four respondents. Anesthesia guidance and fluid status also reflect importance as an application. Respiratory distress received less support. These answers give some light to the needs in the OR, but will have to be tested with a greater amount of participants and anesthesia nurses/technologists. These could be the building blocks of anesthesia applications.

Participants were demonstrated a novel zoom-in/out slide bar prototype (Figure 41). With the slide bar (on the left of the screen), the clinician can zoom in and out of a selected trends time frame. When asked about their perceptions of this concept, the response was very positive. This zooming feature was seen as appropriate for a hand-held device feature, though.

[46] Participant 1, CAB F5

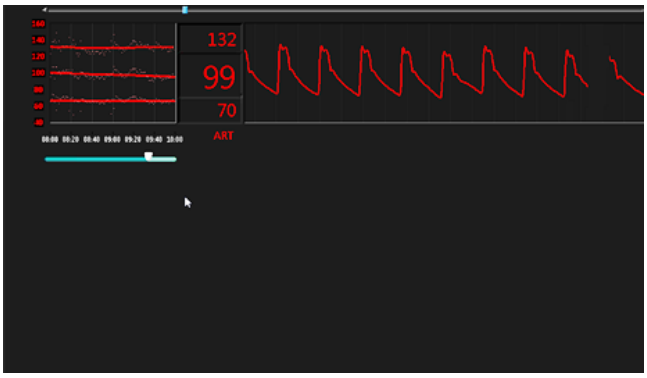

Figure 41: Prototype demonstration screen capture of a potential slide bar feature paired with real time trends.

Participants were also shown a prototype drag/drop mock-up based on a CAB F4 anesthesiologist's suggestion. This feature provides the ability for the clinician to move the screen's attributes to any place on the screen using a drag/drop. This feature received positive feedback (Figure 42). Responses varied, however, on who would be able to configure the monitor with drag/drop (physician, administrator, locked, etc.), and on what screen (direct patient monitor, tablet application, central station, etc.). Safety of the drag-drop solution was also brought up by Participant 5, CAB F5. He stated that with drag/drop, there was a risk that staff may not read the trending labels carefully enough, and thus interpret the information erroneously. He felt that since the OR presents with multiple, simultaneous dynamics, there should be a standard view for all suites, thus eliminating assumptive monitor use. It was also suggested that the monitor log-in screen would create a preference ID; the monitor would know who is using the monitor and configure it accordingly, a wish mirrored from CAB F1.

	Yes	No	Total
Drag-and-drop	4 (100%)	0 (0%)	4
Choose from a menu	2 (67%)	1 (33%)	3

Figure 42: CAB F5 respondents all like the drag/drop feature (n=4).

Another form of early intervention is presented in Figure 43. In this example, a case representing subtle physiological changes over time related to respiratory distress, the monitor is taking raw signal patient monitoring data (top) and transforming the data trend presentation (lower picture). Two clinically relevant parameters are paired and presented simultaneously. On the x-axis, there is a gradient color change from normal (green) to an alarm state (red). The subtle changes in the physiological state of the

patient are easier to identify, and respiratory distress can be identified with CDS long before the alarm state occurs. Theoretically, there would be fewer alarms triggered due to early recognition, as the alarm state would not occur.

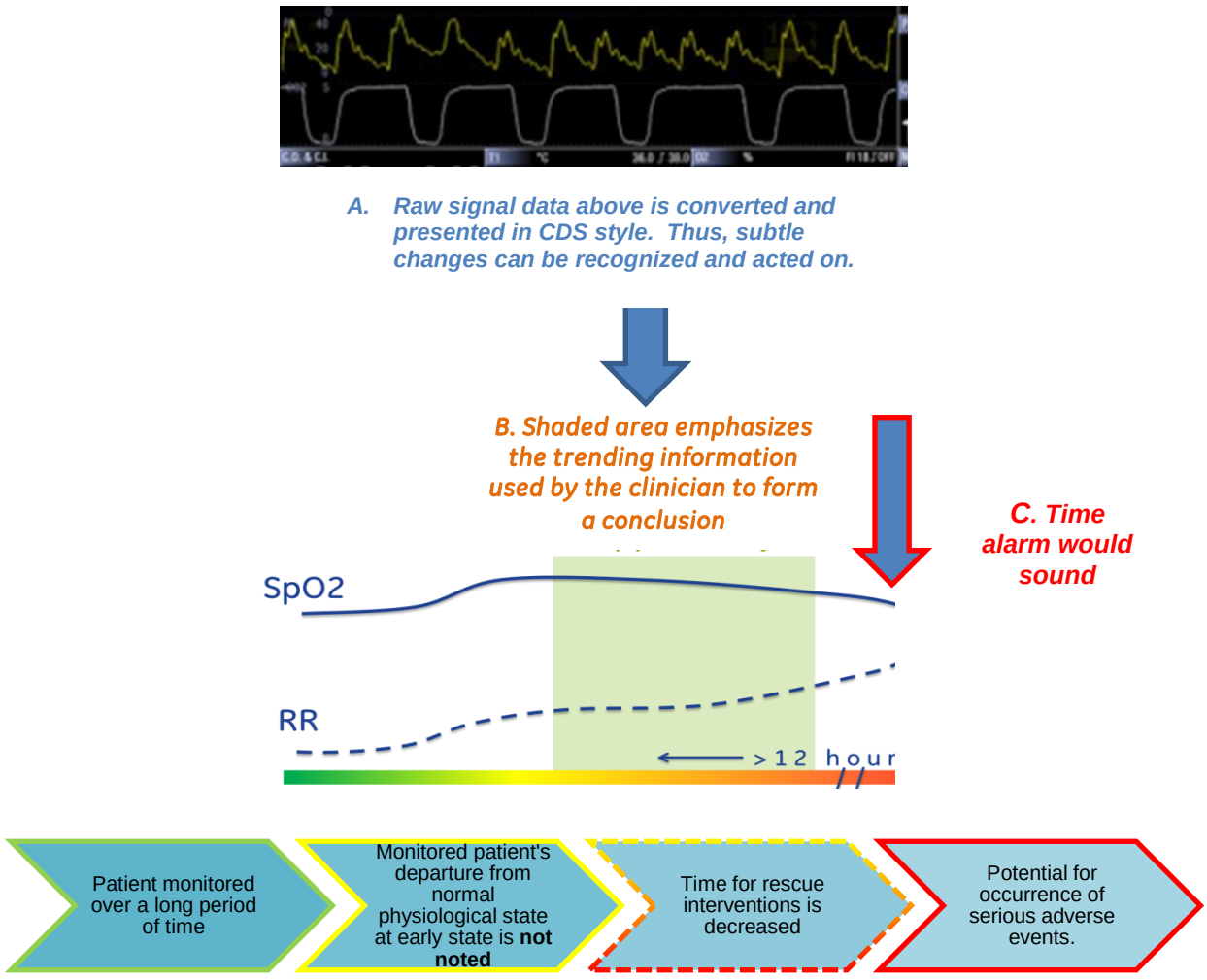

Figure 43: The clinical flow of a monitored patient and the risk for non-recognition of changes in physiological state patterns. This clinical pathway flow could apply to an ICU patient, for example.

In A, the raw data as currently shown on a patient monitor is transformed to the presentation style in B. The adverse changes are evident before the alarm sounds, which is pointed out in C. The lower arrow progression shows a color coded correlation with the bar in B, going from a normal state to the potential occurrence of a serious adverse event.

Figure by the researcher, adapting Tappan's description of adverse events (2009: 223 – 224).

The participants were asked what they felt was missing in the CDS concept. One respondent focused on alerts and ended up with a perception in the difference between nurse and physician usage of the CDS application (and potentially in skill levels) was brought forth:

> *First tier alerts need to be directed at nursing staff not at physicians. The next tier should be for physicians to see the trends that led to the alert so can take action. Grids of info on nursing documentation do not lead to accurate assessment of critical trends until it is a crisis*.
>
> - Participant 4, CAB F5 (MD)

This statement also alluded that the paper version of a chart is not adequate. The "monitor as a chart" concept as discussed earlier was hinted at in that an "*event / intervention summary during OR stay*"[47] was needed in the CDS concept. This, too, supported the "monitor as a chart" theme in CAB F3. Clinicians also stated that they were not interested in the predicitivity feature, saying "*the device should not be prescriptive…the shown example of hypovolemia is not generalizable for hypovolemia…a state to be considered should be shown*"[48]. This statement can be generalized in that pre-configured, named applications may not be as useful as previously thought. This also is mirrored in McKibbon's earlier statement (section 3.4). Many diseases and conditions do not have unique clinical presentations; they share characteristics and clinical presentation. This non-generalization in presentation is also supported in the previous CAB session.

8.7.5 Results CAB F5 Theme 3: PACU and Anesthesia unit differences

As the participants discussed the differences between PACU and anesthesia settings, it was asked in the survey what percent of their time they spent in the PACU, assuming a 40 hour week. All participants spent at least up to 30% of their work week in the PACU (= 12 hours).

The anesthesiologists were asked to rank CDS support tools with elements (Figure 43) moving between the operating room setting and the PACU. The CDS usage mimics the ICU environment in the PACU, while the anesthesia unit appears to depend less on the CDS. In the OR, the father the touch point is from the patient, the less useful it appears to be.

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[47] Participant 2, CAB F5
[48] Participant 1, CAB F5

	Not useful at all	moderately useful	Very useful	Extremely useful	N/A	Total
Do you think that this type of tools would be useful in the OR?	0 (0%)	0 (0%)	4 (100%)	0 (0%)	0 (0%)	4
In the OR, would they be useful in the patient monitor?	0 (0%)	0 (0%)	3 (75%)	1 (25%)	0 (0%)	4
In the OR, would they be useful in the central?	2 (50%)	2 (50%)	0 (0%)	0 (0%)	0 (0%)	4
In the OR, would they be useful on your (mini-)pad?	1 (25%)	1 (25%)	1 (25%)	1 (25%)	0 (0%)	4
In the OR, do you think they would be useful in a smart phone?	0 (0%)	3 (75%)	1 (25%)	0 (0%)	0 (0%)	4
Do you think that this type of tools would be useful in the PACU?	0 (0%)	1 (25%)	1 (25%)	2 (50%)	0 (0%)	4
In the PACU,would they be useful in the patient monitor?	0 (0%)	0 (0%)	2 (50%)	2 (50%)	0 (0%)	4
In the PACU, would they be useful in the central?	1 (25%)	1 (25%)	2 (50%)	0 (0%)	0 (0%)	4
In the PACU,would they be useful on your (mini-) pad?	1 (25%)	1 (25%)	2 (50%)	0 (0%)	0 (0%)	4
In the PACU, do you think they would be useful in a smart phone?	1 (25%)	2 (50%)	1 (25%)	0 (0%)	0 (0%)	4

Figure 44: CAB F5 respondents find the CDS applications at least very useful in all anesthesia and PACU settings. The location of the CDS application is only moderately useful at best in the PACU environment. In all, the farther the touch point from the patient, the less useful the application is deemed. (n=4)

From this, we can propose for future anesthesia / PACU discussions that mobile applications are more important for physicians. The usefulness increases in the PACU environment, which mirrors the intensive care unit, although point of contact is shorter. The total amount of responses and the discussion during CAB F5 give a general context to the anesthesia and PACU environments. Mobile devices such as a smart phone were not seen as useful, although this may be not true for younger anesthesiologists. There was discussion related to the loss of visual acuity with aging, and how seeing information on a small screen is challenging when older. Final decisions related to the usability need further exploration with a larger population of various ages from this practice domain.

8.8 Learning diary usage summary

The researcher kept a learning diary throughout the process. The diary was used to record events and meetings, review details related to data collection and other events, record personal reflective thoughts, and summarize lessons learned. The tool was deemed useful to the researcher, in that it provided an added opportunity for reflection. The research progress was documented in a date-stamped format.

9 Conclusions

This action design research used co-creation of design to determine the clinical end-user's user requirements and clinical application needs related to a novel clinical decision support framework in a multi-parameter patient monitor. The data acquired during five transactional level focus groups, two web-based surveys, and the literature review was analysed, and the CDS user requirements were identified for the company's technology program. The preliminary user requirements for CDS (Appendix 4) were derived from input from a global sample of clinicians representing three professional fields. Profiled users were physicians, respiratory therapists, and nurses who practiced in various hospital settings. The user requirements and CDS applications were assessed and ranked using a novel method created by the researcher for prioritization.

The company's current focus is on creating a Level II CDS solution. The research found that the three Critical to Quality primary needs for a Level II CDS solution are:

- the need for an improvement in trend visualization (via a CDS solution),
- a clinician customizable parameter list, and
- the ability to view CDS remotely from a central station.

The top three pan-clinician user-preferred CDS applications were measured to be sepsis, hemodynamic status, and cardiac events. These were set as the priorities for the research engineering program. However, it would be advantageous to configure all of the potential CDS applications with a similar graphical user interface. Therefore, the list of CDS applications would not be limited to these top three applications but would be clinician configurable so as to fit their own needs.

In addition to answering the research questions, the analysis of the research data led to the determination of the following items related to the CDS solution:

- **CDS solutions would be used to assess for and promote homeostasis in monitored patients.**
- There is the potential for significant cost savings using CDS
- The clinicians would use the CDS solution differently depending on care area.
- The clinicians would use the CDS solutions differently depending on professional background.
- The CDS features would be available pre-configured for a standard view or customized by the user.
- The monitor with CDS should be transformed into a patient charting tool.
- Nurses viewed CDS as an emancipation tool.

- The physicians viewed CDS as a provider of a quick helicopter view assessment tool.
- There is a need to have the monitor integrate care event and procedural information when using CDS.
- CDS could provide early recognition of adverse events, and thus potentially decrease their onset, as slow-onset would be recognized earlier.
- The CDS concept in terms of feasibility, need, and design is supported.
- There is business feasibility for both the CDS concept and technology strategy.
- The systematic collection of clinical user input data and its analysis is necessary to prove or disprove initial Fastworks leap of faith assumptions.
- The purity of a Level II or Level III CDS design may be questionable in practice; the boundaries stated in literature may be blurred in the actuated design.

The use of international, clinical end-users from various clinical settings as focus group participants in an engineering technology group was very fruitful. Although many of the clinicians stated that they were not technical innovators, they proved to be an excellent source of information and guidance. As former GE CEO Jack Welch pointed out in 2014, “innovation is a series of little steps that, cumulatively, lead up to a big deal that changes the game.” Every contact provided valuable information for the research project.

Holding a dual role of clinician and engineering researcher was of unique assistance in the analysis and dissemination of the clinical input for this research. In the future, it should be practice to use this same type of dual-professional as a bridge between engineering and the clinical end-users; someone who understands clinical and engineering methods, actions, and jargon should always be involved in systematic user requirement collection.

The new, Lean-based Fastworks technique worked very well for this type of research program. More data from further focus groups could have been acquired, but the continually positive, uni-directional input gave the engineering team data to proceed. Fastworks can and should be applied to future user requirement collection programs. The use of an on-line survey for both company internal and external respondents was an effective method to acquire data. It should be utilized more frequently by engineering programs.

Although Christiansen’s proposed examples or solutions for healthcare innovation discussed earlier did not include CDS type applications, his ideas of innovation and

successful new-market disruption can be bridged to the CDS framework. CDS would bring formerly hidden or difficult to interpret monitored biophysical signals together as a centralized clinical data package of real-time and historical data. CDS would provide the clinicians with monitor screen views specific to a clinical health event of the patient. In this approach, the disruptive innovation theory pursues the development of sophisticated technology, used to "simplify delivery and treatment and make them fool proof" (Christiansen 2004: 193 - 195), while fulfilling the company's strategic imperative for growth. Adapting the theory of successful up-market sustainability innovation (Christensen 2004: xv – xvii, 9 - 13), the deployment of a patient monitor with a new CDS user interface would provide the clinicians with a new, added-value benefit: enhanced information processing. This increase in functionality and potentially reliability can also be profitable (Christiansen 2004: 9). The case presented in the research shows the potential for great cost-savings using CDS in the healthcare process. This would require further study.

Three of the five steps of user centered design[49] have been met during this research, as was planned. The end-users were defined, the defining user characteristics and desires were recorded, and the findings can be applied to an interface. The next steps of this research will be usability tests and then the final interface.

Further CDS studies could include the validation of user requirements, application usability testing, financial impact, assessment of the change in clinician behaviour, and the determination if CDS causes a change in the patient's clinical outcome (fewer alarms, fewer adverse events, etc.). The prototype testing with different generations of clinical end-users should also be considered.

When the CDS is used, or even set as a default monitor screen view configuration, there is the potential to change the clinical practice of patient monitoring in the hospital, patient outcomes, and clinician monitoring behavior. This research was the first step in actuating the coming evolution in patient monitoring.

[49] Demir et al 2012: 14-17

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Design is a funny word. Some people think design means how it looks. But of course, if you dig deeper, it's really how it works.

—Steve Jobs

Appendix 1: CAB F3 Lecture Materials

The following appendix contains the lecture materials for CAB F3.

note: Appendix 1 has been removed as sensitive material. (19 pages)

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Appendix 2: CAB F3 Survey Form

The following is the text from the web-survey survey form for the CIC VOC collection during CAB F3 prior to the release of the survey.

CDS VOC from CIC

The purpose of the survey is gather feedback related to the CDS concept from people like you with a clinical background.

You responses will be categorized as user feedback, and they may be used as input for user requirements.

Please remember that the CDS is in a research phase, and is company confidential.

Your responses are anonymous.

If you have any questions about the survey, please contact Kristina ([redacted]) for help.

Your answers, especially detailed "free text", are extremely valuable to the team.

Thanks for taking the time to answer the survey!

If you want to review the presentation, it is available at the CIC CoLab site.

Survey Title : **CDS VOC from CIC**

Total Number of Responses: 0

Survey Results Disclaimer:
Survey results may be incomplete, inaccurate, or unreliable, particularly if few or incomplete responses have been received. Consult an Expert when examining, assessing or acting upon survey results. You may not use or disclose survey results for purposes other than the business purpose associated with the survey.

Background information

Q1. Please fill in your academic credentials. (Example RN, BSN or RNC, MN, RT etc.)

No Comment(s) has been entered for this Question.

Q2. Gender		Number of Responses
Male		0
Female		0
	Total	**0**

Q3. How many years have you been a clinician (years since graduation)?	Number of Responses
0-2 years	0
3-5 years	0
6-10 years	0
11 - 15 years	0

16 - 20 years		0
over 20 years		0
	Total	**0**

Q4. What is your clinical specialty? (you can pick more than one!)		**Number of Responses**
Anesthesia (includes all areas, adult)		0
Anesthesia (includes all areas, pediatrics)		0
Cardiac ICU		0
ICU		0
ER /Trauma		0
PICU		0
NICU		0
Medical / Surgical		0
OB GYN/ L&D		0
Transport/flight		0
Step-down		0
Neurology		0
Other		0
View Explanation(s)	**Total**	**0**

Q5. How long have you worked at [redacted] (includes time included if acquisition)		**Number of Responses**
0-2 years		0
3-5 years		0
6-10 years		0
over 10 years		0
Other		0
View Explanation(s)	**Total**	**0**

Q6. What is your current role at [redacted]?

No Comment(s) has been entered for this Question.

Q7. Are you working in a clinical setting in addition to your work at GE? If yes, please elaborate in the "other" section.		**Number of Responses**
Yes		0
No		0
Other		0
View Explanation(s)	**Total**	**0**

Q8. What is your geographic location? (If you want to be more specific, you can add information under "other")	**Number of Responses**
North America	0
Latin America	0
South America	0
Europe	0
Africa	0
Middle East	0
Asia	0
Australia/ New Zealand	0

Other		0
View Explanation(s)	**Total**	**0**

Q9. What, in your opinion, is the biggest improvement need for patient monitors today? This can be anything: display, alarms, ease of use, data continuity - - anything. And Why??

No Comment(s) has been entered for this Question.

Clinical Decision Support (CDS) concept

Q10. How favorable was the CDS concept to you as a clinician?		**Number of Responses**
not at all		0
somewhat		0
neutral		0
quite interesting		0
very interesting		0
View Explanation(s)	**Total**	**0**

Q11. Please rate the following features

	Not needed at all	Low importance	Moderate importance	High importance	Critical requirement	**Total**
Improve trend visualization	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Utilize calculated parameters (for example cc, pc, etc)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Show interrelationships between parameters (=stacking")	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Customizable Layout	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
customizable parameter list	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Customizable amount of screen used for trends vs real time	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Availability of pre-configured templates/protocols (sepsis view, stroke view etc, respiratory view)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Ability to adjust trend data display (% of screen or retrospective time) shown concurrently with real time data	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Ability to view CDS to a mobile device	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Ability to view CDS to a central station	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**

Q12. How do you feel CDS would be useful? You can give patient cases, types of information etc.

No Comment(s) has been entered for this Question.

Q13. If there was CDS available, how frequently do you think it would be used (by a practicing clinician)?	**Number of Responses**

Never		0
Rarely (not every patient, maybe not even daily)		0
Occasionally (maybe daily, at least a few times a week, some patients)		0
Frequently (at least a few times per shift, most or all patients)		0
Always (daily, all patients)		0
I would want it as the primary default view for all of the patients		0
Other		0
	Total	**0**

Q14. How would you use CDS?
Here are some examples, but you can be creative:
look at more specific trending, review pharmacological interaction, guide your care, look at your patient's state from different viewpoints, follow therapeutic interventions, etc

No Comment(s) has been entered for this Question.

Q15. Do you feel physicians and nurses would use the CDS differently? Please explain your answer in the "other section".		**Number of Responses**
Yes		0
No		0
Other		0
View Explanation(s)	**Total**	**0**

Q16. Please tell, from a nursing perspective, how you would want information provided so that it is usable and actionable.

No Comment(s) has been entered for this Question.

Q17. Please check all of the CDS clinical concepts you feel would be important in clinical use (as "available licenses"/ packages in the monitor). If something you feel is needed is missing, please add it to the "other" section.		**Number of Responses**
Sepsis		0
Stroke		0
Cardiac events		0
Ventilator weaning		0
Stroke		0
Oxycardiorespirogram		0
Neurological status		0
Hemodynamic status		0
Oxygenation status		0
Other		0
View Explanation(s)	**Total**	**0**

Q18. Please pick the TOP THREE CDS clinical concepts you feel would be most important(as "defaults" in the monitor).If something you feel is needed is missing, please add it to the "other" section.		**Number of Responses**
Sepsis		0
Stroke		0
Cardiac events		0

Ventilator weaning		0
Stroke		0
Oxycardiorespirogram		0
Neurological status		0
Hemodynamic status		0
Oxygenation status		0
Other		0
View Explanation(s)	**Total**	**0**

Q19. What non-monitoring items would you want to have included in a CDS view? (pick as many as apply, you can add free text to the "other" field.)		**Number of Responses**
Laboratory values		0
Care events or procedures		0
Ventilator information (settings)		0
O2 information		0
Anesthesia information (settings and gases)		0
Comment area		0
Scoring (for example Glasgow coma scale, pain scale)		0
Pharmaceuticals IV		0
Pharmaceuticals (other)		0
Radiology procedure at the bedside		0
Imaging results		0
Other		0
View Explanation(s)	**Total**	**0**

Q20. What TOP THREE non-monitoring items from the list above would you want to have included in a CDS view? (pick only your top three, you can add free text to the "other" field.)		**Number of Responses**
Laboratory values		0
Care events or procedures		0
Ventilator information (settings)		0
O2 information		0
Anesthesia information (settings and gases)		0
Comment area		0
Scoring (for example Glasgow coma scale, pain scale)		0
Pharmaceuticals IV		0
Pharmaceuticals (other)		0
Radiology procedure at the bedside		0
Imaging results		0
Other		0
View Explanation(s)	**Total**	**0**

Q21. Would you want your monitor to give you care reminders? You can give example in the "other" field.		**Number of Responses**
Yes		0
No		0

Other		0
	Total	**0**

Q22. IF CDS was so advanced it could give you predictive analytics ("because of XYZ, sepsis probable, consider blood cultures and starting antibiotics"), how comfortable would you feel with trusting the analysis?	**Number of Responses**
Not at all	0
Somewhat, yet slightly sceptical	0
I would be trusting, yet still look for more information	0
I would trust that this is the best pathway	0
I would not want a monitor to give me clinical advice	0
Total	**0**

Q23. If you know someone GE internal who would be able to provide input for this survey, please send them the link you were provided with.

Any other comments you would like to add, please do so below!

No Comment(s) has been entered for this Question.

:: END OF SURVEY ::

Appendix 3: CAB F5 Survey Form

The following is the text from the web-survey form for the VOC collection during CAB F5 prior to its release.

Perioperative Clinical Advisory Board March 2014

Questions related to the Clinical Decision Support discussed during the CAB.
Your responses are anonymous.
Thank you for taking time to answer the survey!

Survey Title : **Perioperative Clinical Advisory Board March 2014**

Total Number of Responses: 0

Survey Results Disclaimer:
Survey results may be incomplete, inaccurate, or unreliable, particularly if few or incomplete responses have been received. Consult an Expert when examining, assessing or acting upon survey results. You may not use or disclose survey results for purposes other than the business purpose associated with the survey.

Background info

Q1. What is your geographical region?		**Number of Responses**
Asia		0
Australia/New Zealand		0
Europe		0
North America		0
	Total	**0**

Q2. What is your gender?		**Number of Responses**
Male		0
Female		0
	Total	**0**

Q3. How long have you been in active clinical practice?		**Number of Responses**
0-5 years		0
6 - 10 years		0
11-16 years		0
over 17 years		0
	Total	**0**

Q4. Your primary care area is the anesthesia suites. How much percent of your time do you spend, on average during a 40 hour work week, in the PACU?		**Number of Responses**
0 - 10%		0
11-20%		0
21-30%		0

31-40%		0
41-50%		0
51-60%		0
61-70%		0
71 - 80%		0
81 - 90%		0
91-100%		0
	Total	**0**

Q5. Which EHR system is your hospital using?

No Comment(s) has been entered for this Question.

Q6. How satisfied are you with the EHR system your hospital uses, and why?

No Comment(s) has been entered for this Question.

Q7. How interesting was the CDS concept to you as a clinician?		**Number of Responses**
Not at all interesting		0
Somewhat interesting		0
Fairly interesting		0
Very interesting		0
	Total	**0**

CDS usefulness

Q8. We showed examples of clinical decision support tools that would contain elements such as those shown in picture one attached to the mail the survey link came with.
(The concrete examples were about detecting cardiac ischemia, hypovolemia, respiratory distress).

	Not useful at all	moderately useful	Very useful	Extremely useful	N/A	**Total**
Do you think that this type of tools would be useful in the OR?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the OR, would they be useful in the patient monitor?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the OR, would they be useful in the central?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the OR, would they be useful on your (mini-)pad?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the OR, do you think they would be useful in a smart phone?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Do you think that this type of tools would be useful in the PACU?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the PACU,would they be useful in the patient monitor?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the PACU, would they be useful in the central?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the PACU,would they be useful on your (mini-) pad?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
In the PACU, do you think they would be useful in a smart phone?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**

	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**

Q9. Which of the following applications you would use in the OR?

	Most important	Very important	Moderately important	Not very important	Least important	N/A	Total
Anesthesia guidance	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Cardiac function, hemodynamics	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Fluid status	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
Respiratory distress	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**

Building blocks

Q10. Please take a look at picture number one again. Is there something there that you would not use in the OR? (you can pick more than one)	**Number of Responses**
1	0
2	0
3	0
4	0
5	0
I could envision using them all in different situations	0
Total	**0**

Q11. Still related to picture number one, what is missing from the building blocks for OR use?

No Comment(s) has been entered for this Question.

Q12. Still looking at picture number one, is there something you would not use in the PACU? (you can pick more than one)	**Number of Responses**
1	0
2	0
3	0
4	0
5	0
I could envision using them all in different situations	0
Total	**0**

Q13. Still related to picture number one, what is missing from the building blocks for PACU use?

No Comment(s) has been entered for this Question.

Tools for CDS

Q14. We showed a sliding bar to flexibly adjust between the portions of trend data and real-time data.Would this be a useful feature in the:

	Yes	No	N/A	Total

OR patient monitor?	0 (0%)	0 (0%)	0 (0%)	**0**
OR Central station?	0 (0%)	0 (0%)	0 (0%)	**0**
OR tablet/pad device?	0 (0%)	0 (0%)	0 (0%)	**0**
PACU patient monitor?	0 (0%)	0 (0%)	0 (0%)	**0**
PACU Central station?	0 (0%)	0 (0%)	0 (0%)	**0**
PACU tablet/pad device?	0 (0%)	0 (0%)	0 (0%)	**0**

Q15. We showed drag-and-drop manipulation of parameter configurations to create different views (such as general view, cardiac function, fluid balance, respiration) on the screen. Would you prefer:

	Yes	No	Total
Drag-and-drop	0 (0%)	0 (0%)	**0**
Choose from a menu	0 (0%)	0 (0%)	**0**

Q16. We suggested that clinicians could be able to easily configure the different views by drag-and-drop. Who should be able to configure these at the patient monitor level? (you can pick more than one)	**Number of Responses**
Person at the patient monitor (nurse, physician)	0
Head of the department	0
Each person has unique configuration based on identity	0
Central location	0
No configurability, everything fixed	0
Other	0
Total	**0**

Q17. We suggested that clinicians could be able to easily configure the different views by drag-and-drop. Who should be able to configure these at the central station level? (you can pick more than one)	**Number of Responses**
Person at the patient monitor (nurse, physician)	0
Head of the department	0
Each person has unique configuration based on identity	0
Central location	0
No configurability, everything fixed	0
Not applicable, we don't have a cnetral station.	0
Other	0
Total	**0**

Q18. We suggested that clinicians could be able to easily configure the different views by drag-and-drop. Who should be able to configure these at the (mini)pad/mobile	**Number of Responses**

device level? (you can pick more than one)	
Person at the patient monitor (nurse, physician)	0
Head of the department	0
Each person has unique configuration based on identity	0
Central location	0
No configurability, everything fixed	0
Other	0
Total	**0**

Q19. Imagining that there is an easy drag-and-drop to use, please answer the following questions.

	Never	Very rarely	Occasionally	May do this somewhat of the time	I would like to do this quite often	Total
How often would you want to finetune the views yourself?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**
How often would you like to create your own views for a particular decision making context?	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**0**

The future is now

Q20. What trends do you envision or concerns do you have about the future of anesthesia monitoring?

No Comment(s) has been entered for this Question.

Close Window Back

Appendix 4: User Requirements for the CDS

The following are (Preliminary) User Requirements for CDS in the technology phase of the CDS program in the technology phase based on input from users. These must be reviewed and may be revised during integration to product programs. They are based on this research and its analysis. The User Requirement format is in a style dictated by the company.

Some sections, such as frequent use scenarios, are to be developed further at a later stage of program development, as a functioning CDS is available for assessment and usability testing. Current examples are taken into consideration, but the final input will be available concurrently with a functioning CDS.

The final worst case scenarios are dependent on the final design, and mitigation efforts are defined in the final product requirements and/or software requirements, and/or user requirements. The linkage will then be made to the product's Cause Mitigation Table (risk management document) per ISO 14971 (Risk management for medical devices) and company procedures and work instructions.

:::

Purpose

This document is a user requirements specification of Clinical Decision Support (CDS).

Description of the device

CDS is a software only data presentation tool option for use during multiparameter monitoring of a hospitalized patient.

The CDS is for use by qualified medical personnel only.
Note: the clinical user needs a host monitor with software TBD base level version TBD to have a functioning CDS.
The word User refers to the clinical end-user of the product.
The patient does not have contact with the CDS as a user.

References

Process Related Documentation, internal company documents

[AD1] Design Controls Design Inputs Work Instruction, DOCXXXXXXX

[AD2] Design Controls Design Validation Work Instruction, DOCXXXXXX

[AD3] Design Controls Usability Work Instruction, DOCXXXXXX

Program related documentation

[R1] CDS Program plan DOC XXXXXX

[R2] Environment Profiles for Patient Monitors DOCXXXXXX

[R3] User Profiles for Patient Monitors DOCXXXXXXX

User Needs

The clinical user needs a method of obtaining intelligently filtered, prioritized and actionable information visualized in a clinically relevant manner.

CDS Requirements

ID	REQUIREMENT
UR_001	The user shall have the ability to use CDS trend visualization when the CDS software is activated in the monitor.
UR_002	The user shall be able to customize the CDS parameter list.
UR_003	The user shall be able to view CDS at the central station.
UR_004	The user shall be able to combine parameters into trend views with CDS.
UR_005	The user shall be able to view the CDS application from a mobile device.
UR_006	The user shall be able to adjust the trended data display
UR_007	The user shall be able to chose CDS views from all available parameters
UR_008	The user shall be able to chose views from preconfigured templates
UR_008	The user shall be able to combine at least two parameters
UR_010	The user shall be able to adjust the amount of screen user for trends vs real time signals.

CDS Accessory requirements

There are no accessory requirements for CDS.

Intended Use

The CDS is intended for use with modular multi-parameter monitors.

Indications for use

The CDS is indicated for general patient monitoring as a trend view.

The monitoring device and its software is indicated for use by qualified medical personnel only.

Labeling (clinical claims for CDS)

There are no clinical claims for CDS.

User instructions

ID	REQUIREMENT for CDS
UR_200	The User shall have user instructions for the CDS when used with a host monitor.

User maintenance

There is no maintenance to be done by the user.

Cleaning the CDS

This section is not applicable, as CDS is software only.
There are no cleaning requirements for the CDS.

Patient Needs

This section is not applicable. The CDS does not include features that are intended for use directly by a patient.

Human Factors, Ergonomics, and Product Usability

Reference: Design Controls Usability Work Instruction (DOC XYZ).

Primary Operation Functions

ID	REQUIREMENT
Usab_400	User shall be able to use CDS as an optional part of the monitoring system when the CDS application is activated in a host monitor.

Frequent use scenarios

ID	Frequent Use Scenario (FUS)
Usab_410	FUS with OR nurse, anesthesia including: trending, alarm, set-up, change % of screen *Note: incorporate FUS test cases using all of the UR*
Usab_411	FUS with ICU nurse including: trending, pages/views, alarm, set-up, change screen, Central *Note: incorporate FUS test cases using all of the UR*

Usab_412	FUS with PACU nurse including: trending, pages/views, alarm, set-up, change screen, Central *Note: incorporate FUS test cases using all of the UR*
Usab_413	FUS with OR MD, anesthesia including trending, pages/views, alarm, set-up, change screen, Central (actual and mobile device) *Note: incorporate FUS test cases using all of the UR*
Usab_414	FUS with ICU MD including: trending, pages/views, alarm, set-up, change screen, (actual and mobile device) *Note: incorporate FUS test cases using all of the UR*
Usab_415	FUS with anesthesia MD switching between PACU and anesthesia (actual and mobile device) *Note: incorporate FUS test cases using all of the UR*

ID	Use scenario
Case_1_ICU_adult	Actors: ICU Nurse (case 1A) and ICU physician (case 1B) Patient data: 58 year old male ICU patient with full monitoring, cardiac patient, ventilated, sedated, vasopressors, IV cardiac support meds. User to assess the following items: 1. Oxygenation status 2. ECG ST changes vs oxygenation status 3. Sedation level 4. Patient stability over last 12 hours 5. Hemodynamic stability Observer notes all actions of actor.
Case_2_NICU_neo	Actors: NICU Nurse (case 2A) and ICU physician (case 2B) Patient data: 32 week gestation female at day 3, nasal CPAP, tube feeding, small vasopressor IV, apnea episodes. User to assess the following items: 1. OCRG for past 12 hours 2. OCRG in relation to feed times 3. Sepsis indicators for past 23 hours Observer notes all actions of actor.
Case_3_OR_adult	Actors: Nurse anesthetist (Case 3A) and Anestesiologist (case 3B) Patient data: 35 year old male with lung resection, history of asthma. User to assess the following items: 1. Cardiac status 2. Oxygenation status 3. Hemodynamic status Observer notes all actions of actor.

(Reasonable) foreseeable worse case use scenarios

ID	REQUIREMENT
Usab_420	(these are developed from the risk analysis and includes all professions, linked to product and/or software and/or user requirements in the product's final cause mitigation table)
Usab_425	(these are developed from the risk analysis and includes all professions, linked to product and/or software and/or user requirements in the product's final cause mitigation table)

Note: there may be more than two in the final version

Use environment and description of the user(s)

The CDS is used by qualified medical personnel as a method to observe trended data from a multiparameter patient monitor used while monitoring hospitalized patients. CDS is for use by qualified medical personnel (nurses, respiratory therapist, and physicians) only. The CDS is intended for use on one patient at time.

For more information of the users and environments, refer to:

User profiles for patient monitors	DOCXXXXX
Environmental Profiles for patient monitors	DOCXXXXX

Cleaning the accessories

This section is not applicable, as there are no dedicated accessories for CDS.

Incident search

As CDS is a new product, there is no feedback for consideration for an incident search of prior products.

END OF USER REQUIREMENTS