Time & frequency alignment of multi-parameter real-time physiological and related data is necessary for reliable clinical decision making.

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The Challenge

• Real-time clinical decision support systems require accurate, high-frequency data to ensure high-quality decision making
• Many devices that are not on Gateways or possess common timing and synchronization services can be off in terms of absolute time, vary in terms of data time alignment, and may provide readings that can be misinterpreted if not calibrated prior to use.
• The specific concern is over integrating data from multiple devices that are not calibrated to common times or do not provide data on common time windows (and asynchronously), as these data, if un-validated and un-calibrated, can cause misinterpretation or reading of clinical data for clinical decision support purposes.
• These points, combined with varying data availability requirements, can potentially lead to an inaccurate assessment of the true state of patient state in high acuity settings.
Devices Supporting Acute Care Environment
Clinical Decision Making is Based Upon Multiple Data Sources

Key Parameters Used to Determine Action

Clinical Decision Support Systems

Data from multiple sources (enterprise and departmental health systems, devices, etc.)

(Note: NOT simply a linear sum of elements, but a system of mutually-satisfied constraints)
Examples of Multi-Parameter Medical Device Data
(e.g. use case: management of weaning and spontaneous breathing trials)

- **f<sub>R</sub> (br/min)**
  - Mandatory: 12
  - Spontaneous:

- **CO (l/min)**
  - 3

- **Nitropusside (u/kg/min)**
  - 0.5

- **HR (l/min)**
  - 88

- **Time, in hours**
  - Absolute time alignment

**Tc(C)**
- 37
Synchronous and Asynchronous Data Collection

- **$f_R$ (br/min)**: 12
- **$V_T$ (l/br)**: 0.5
- **CO (l/min)**: 3
- **Tc(C)**: 37
- **HR (l/min)**: 88
- **Nitropusside (u/kg/min)**: 0.5

Time, in hours
Synchronous and Asynchronous Data Collection
Common time point for decision making – ordering reduction in support

Data availability and staleness in relation to decision making can influence decisions
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Decision support systems may require higher-fidelity data or more frequent collection
Synchronous and Asynchronous Data Collection

Common time point for decision making — ordering reduction in support
— Shifted timelines, poor alignment on specific clinical events, lack of collection —

Complicated by situations in which absolute time representations on devices deviate from some standard benchmark
Potential Hazards

- Misaligning vitals state data that, when integrated or fused together, could impact clinical decision making (e.g.: potentially impacting the interpretation of patient state);
- Inaccurately recording information in clinical documentation and orders based on time differences among devices (timing of infusion changes versus changes in mechanical ventilation setting adjustments);
- Data not collected on one system because time threshold not met based on local time reference of device with respect to its synchronous recording interval;
- Particular data not recorded upon notable events because asynchronous in nature with respect to data collected from synchronous systems;
- Errors in charting of information by two or more different clinicians viewing data at near the same wall clock time, but recorded based on differences in device internal clocks.
Impacts? Real-Time Clinical Decision Support

• Cardiac Output changes with respect to sodium nitroprusside levels
  – Early reduction in vasodilator levels can lead to cardiac output (C.O.) reduction, decompensation and distress;
  – Associating changes in infusion of specific drips with cardiovascular performance requires timely knowledge of both infusion and C.O., heart rate (changes in C.O. can occur in just a few seconds)
  – Decision support algorithms require latest information on both to recommend action

• Spontaneous breathing rates and rapid shallow breathing with respect to changes in mandatory support levels
  – Sudden increases in RSBI after changes in support levels are indicators to notify staff of need for intervention
  – Need for suctioning and events surrounding intubation can occur suddenly and decision support algorithms require synchronous information on spontaneous parameters and work of breathing together with temperature

• Decision to reduce support levels driven by multiple parameters
  – Change in pH and end-tidal CO2 levels influence respiratory support levels.
  – Determination of changes in support may require latest information on blood gases and (from Swan) invasive cardiac and real-time blood gas parameters
  – Need for updated blood gas data (pH, PCO2, B.E., HCT, etc.) can be triggered by need for a CDSS to operate on new data (i.e., recommend spontaneous breathing trials subject to result of latest blood gas)
  – Changes in systemic vascular resistance (SVR) leading to variation in cardiac output can occur due to sympathetic and parasympathetic tone changes (and through infused drug) in less than 1 second.
Synchronous and Asynchronous Data Collection

Trigger queries for data to fill missing gaps based on common system time

- **$f_R$ (br/min)**
- **$V_T$ (l/br)**
- **$CO$ (l/min)**
- **Tc(C)**
- **HR (l/min)**
- **Nitroprusside (u/kg/min)**

Trigger queries for data to fill missing gaps (that is RECEIVING system requests missing data) to update parameters requested by rules algorithms automatically based on gaps in existing data.
Support “gap-filling” capability for automatically requesting missing information if not within some specific timing or frequency threshold.

Synchronous Data Communication

CDSS evaluates multiple parameters, determines relevance and importance of each with respect to specific condition being tested (example: spontaneous breathing trials).

Support query for parameter that does not meet certain criteria on currency, or for which data are lacking.

Initiate query for missing data to appropriate target device.