Summary

In standard practice in most hospitals, terabytes of physiological data collected on patients simply disappears from bedside monitoring platforms after a few days. While a tiny number of derived measures, such as heart rate, are documented in the EHR for clinical care, many researchers have recognized the potential utility of high-resolution clinical data for deep phenotyping, physiological state monitoring, risk stratification, adverse event prediction, precision medicine and situational awareness.

At Lurie, several groups of researchers have explored the value of high-resolution physiological data, starting with the work of Drs. Debra Weese-Mayer and Michael Carroll in Autonomic Medicine[1–6] and extending through the NICU Pre-Vent project[7]. Similarly, the big data approach originally championed by Drs. Mike Kelleher and Mark Wainwright[8] in the PICU and CCU has been carried forward in a range of new projects driven by Drs. L. Nelson Sanchez-Pinto (with a strong background in big data analytics[9–12]) and Marcelo Malakooti. Additionally, two recently recruited anesthesiologists, Drs. Ken Brady and Eric Vu, have brought a strong research portfolio based on intraoperative and CCU physiological recordings[13–18]. At the same time, several Lurie researchers have developed collaborations with the John Rogers group at NU using wireless skin interface wearables[19,20]. In short, there is a large group of Lurie investigators actively pursuing research in high-resolution physiological data analytics. Table 1 summarizes this activity.

Recently Completed

Stream	Project	Funding Source	Faculty
Wearables	Wireless NICU	Friends of Prentice	Paller, Weese-Mayer, Hamvas
	Low Resource Infant Monitoring	Gates Foundation	Weese-Mayer

Current and Pending

Stream	Project	Funding Status	Faculty
Autonomic /NICU	Pre-Vent	U01 Ongoing	Weese-Mayer, Carroll, Hamvas, DeRegnier
	Post-Vent	U01 Submitted	Hamvas, Weese-Mayer,
	Cerebral Autoregulation	Admin supplement Awarded	Weese-Mayer, Vu, Brady
Perinatal Origins	Promoting Healthy Brains	Research Strategic Initiative	Hamvas, Wakschlag
PICU	Integer HRV / PICU Acuity	K Planned	Badke, Sanchez-Pinto
	Fluid Response	K Planned	Walker, Sanchez-Pinto
	Dashboard Decision Support	IGNITE Support Ongoing	Malakooti
	ED/PICU Sepsis	R Planned	Sanchez-Pinto, Alpern, Carroll
CICU/Anesthesiology	Cerebral Hypoperfusion	RO1 Awarded	Brady, Marino, Vu

Wearables	Surgical Complications: Appendectomy	RO1 Submitted	Abdullah, Ghomrawi
	Surgical Complications and 7 Procedures	RO1 Submitted	Abdullah, Ghomrawi
	NICU BP Wearable	Gerber Foundation Ongoing	Weese-Mayer, Hamvas
	Father Kangaroo Care	Internal Ongoing	Garfield, Weese-Mayer
	Toddler Actimetry	Admin supplement Awarded/R01 submitted	Kwon, Honegger

Table 1. Summary of research activities using physiological data from bedside monitors or wearable sensors.

Despite this core of interested physicians and scientists, including many with external funding, the overall research program has been hampered by several barriers. In many cases because these projects have developed through distinct divisions (Pediatrics, Surgery, Anesthesiology, SCHORE) and departments (PICU, CCU, NICU), and have received support from a variety of internal and external sources (Research Strategic Initiative, NIH, etc.), there has been a lack of coordination and resource sharing between these projects. Similarly, because of the ad hoc development of these projects over the years, the underlying technological infrastructure for bedside data has become fragmented, with three main systems now in use: BedMaster (in the NICU and PICU), Sickbay (in the CCU and cardiac procedure ORs) and Etiometry (for clinical use in the CCU). Each has different capabilities, data formats and access methods, making interdisciplinary projects cumbersome and creating duplicative effort for support departments. For wearables data, no set infrastructure has been developed (though there has been some pilot testing).

Integration and consolidation of the technological infrastructure, along with collaboration between groups and improved governance would drive research productivity while providing an infrastructure that could also support important data-driven clinical and quality initiatives.

Proposal: Unification of infrastructure underlying big data physiology at Lurie, and creation of a Physiological Analytics Core that would coordinate research activities while exploring advanced clinical and quality applications of these technologies in order to develop a kind of physiological precision medicine.

Objectives:

I. **Infrastructure:** Unify bedside data collection within a single vendor infrastructure while developing a fully integrated analytics/visualization pipeline that can support research, quality and clinical applications using data from bedside monitors, wireless wearables and asynchronous telemetric sources.

II. **Coordination, collaboration and governance:** Enhance interdisciplinary research networking within Lurie and collaborations with NU researchers with shared interests. Continue governance efforts to guide predictive modeling and clinical decision support as well as bedside technology implementations that span research, clinical and quality applications.

III. **Clinical/quality applications:** Coordinate with clinicians to deploy high-resolution physiological analytics capabilities for situational awareness and decision support. Coordinate alarm rationalization program within Nursing, Clinical Informatics and the Center for Excellence.

Plan

I. Infrastructure:

A. Unification of bedside data acquisition systems: With the arrival of Sickbay, we now have three main bedside data analytics systems in use (with yet another system in the ORs). Though there are some unique capabilities of each of these, there is also a great deal of overlapping functionality, so maintaining these distinct systems comes at considerable institutional cost. In addition to the simple added overheard of maintaining servers and networks, there are duplicative training and support efforts. Similarly, accessing the data for retrospective analysis requires three different methods, adding significantly to the difficulty of merging data sets from different clinical units with different systems. The Medical Device and Data Integration Committee (MDADI) has solicited responses from 4 vendors based on key capabilities of these system for research, clinical and quality applications. The Committee is prepared to recommend Sickbay to EPMO/MCOC as a replacement for BedMaster in the NICU and PICU, thereby establishing a robust acquisition and analytics platform in NICU, PICU, CCU and all OR suites. Interest in Sickbay has also been noted from Dr. Libby Alpern for the ED and Dr. Weese-Mayer for CAMP.

B. Retrospective data analytics platform: The vast majority of time spent on analysis of physiological data is spent finding, moving, normalizing and reconciling the time bases on different signals. **A well-designed platform for organizing, visualizing and running analytics on data from cohorts of patients can accelerate research as well as quality improvement initiatives.** Clinical care and situational awareness can also be improved by the ability to review historical data from particular patients or from patients with similar conditions. If deployed more broadly, the Sickbay system can support some of these functions, but access to historical BedMaster data will continue to require a separate system.

C. Streaming analytics and visualization platform: As mentioned above, **analysis of high-resolution bedside data with modern data science methods has the potential to develop a kind of physiological precision medicine** that would contribute to clinical decision support and situational awareness, especially in critical care. To develop these tools Lurie needs a platform for real-time analytics visualizations, including dynamic risk scores, predictive trajectories, integrative displays including EHR data and intervention modeling. Sickbay provides some of these capabilities, and DAR has been working to develop a framework for BedMaster data, but we need to adopt or develop a flexible platform for prototyping, testing and deploying these tools in the field.

D. Wireless/Wearables infrastructure: An integrated platform to capture, store and process continuous data from wireless/telemetric sensors from inside and outside the hospital would provide a platform for a transformational research program. Lurie's on-going collaborations with the Rogers Lab provide a unique opportunity to explore pediatric applications of his nationally recognized work. Such a platform would also support clinical applications, as in Dr. Fizan Abdullah's recent EPMO proposal to use wireless activity data to track surgical recovery. Analysis of ambulatory telemetric data (as exemplified by the Promoting Healthy Brains Project) would also be supported as well as data such as that acquired in Drs. Carolyn Foster and Soyang Kwon's work[21].

Current Support

Goal	Time Frame	Current Status	Requested Support	Requested Support Source(s)
Replace BedMaster with Sickbay in NICU and PICU	FY21Q4	Ongoing support from DAR	Reallocation of BedMaster ongoing support resources	DAR Internal (Additional server/network infrastructure may require some IM resources)
Platform Development	Ongoing	Currently supported by DAR-Research under RSI	Data Architect 1.0 FTE	Continued support under Stanley Manne/Renewed RSI
Data Management	Ongoing	Currently supported by DAR-Research (POD: PHBP)	Data Manager 1.0 FTE	Continued support under Stanley Manne/Renewed RSI
PICU Data Support	FY21	To be supported by IGNITE/Neurocritical Care	Data Analyst 1.0 FTE co-report with DAR	IGNITE/Neurocritical Care
Coordination/Supervision	Ongoing	Currently supported by DAR-Research under RSI	CIVL Director 0.3 FTE	Continued support under Stanley Manne/Renewed RSI

Net New Requested Support

Goal	Time Frame	Current Status	Requested Support	Requested Support Source(s)
Deploy Sickbay in ED and CAMP	FY22Q1		Support licenses	Departmental Research Funds
Deploy Ancillary Device Integration for Sickbay	FY22Q3		Hardware connections and cables; ongoing tech support	EPMO
Wireless Sensor Data Ingestion	FY21Q4	Current pilot in EPMO for Dr. Abdullah's work	Infrastructure for ingestion and analytics	EPMO
Streaming Data Interface Development	FY21		Consulting ($50K)	DAR Research (RSI)
Streaming Data Interface Development	FY22Q1		Front End Developer 1.0 FTE	IGNITE/Brady

II. Coordination, collaboration and governance:

A. Research Collaboration: As mentioned above, bedside data (and similar data from wearable devices) is already an integral element of several strains of externally-funded research at Lurie (Table 1). DAR also looks forward to collaborating with our colleagues in Anesthesiology, Drs. Brady and Vu, on an R01 grant based on data from Sickbay in the CCU. While the loss of Dr. Marsillio has been a tragic setback in DAR's PICU-based research collaborations, we continue to pursue a diverse set of promising projects in that department with Drs. Sanchez-Pinto, Malakooti, Badke, Walker and others. In particular, Dr. Badke's work (manuscript in submission) shows the potential of continuous bedside data as a predictor of organ dysfunction. DAR can further facilitate research collaborations by developing a seminar series under the Analytics Network to include researchers interested in physiological data applications.

B. Governance: DAR and IM currently host a committee to guide deployment of predictive models and risk scores within the EHR. The charter can be expanded to insure institutional review of real-time physiological analytics deployed in clinical settings. DAR and HTM also work together with IM on the MDADI Committee, which helps guide implementation of bedside informatics technology under MCOC.

Current Support

Goal	Time Frame	Current Status	Requested Support	Requested Support Source(s)
Collaboration Seminar Series	FY21Q3		PM support for research seminar series	DAR Internal
Collaboration Seminar Series Development	FY21Q3	Currently supported by DAR-Research under RSI	CIVL Director 0.1 FTE	Continued support under Stanley Manne/Renewed RSI

III. Clinical/quality applications:

A. Trended vitals visualization: Many critical care physicians believe that the ability to view trended vitals over hours or days can transform care, especially if those displays can show those vitals in the context of other EHR data (such as labs or medications). In some other institutions, data archival systems have also been used for mortality and morbidity reviews to understand the full physiological context of clinical events.

B. Alarm rationalization: Systems like Sickbay and BedMaster are also capable of integrating data from ancillary devices such as ventilators. Data and alarms from these devices can then be pushed to the EHR or messaging systems like Connexall. Barbara Fleming (NICU APN) and Dana Evans (Director of Respiratory Services) have long advocated to make this connection a standard of care so that ventilator alarms could be surfaced in messages to providers in locations where the audible alarms may be difficult to hear. More generally, **the most significant potential clinical application for bedside data systems is for alarm rationalization.** These systems can integrate alarm data from different devices along with simultaneous vitals and EHR data, meaning that alarms could be more easily tailored to the specific physiological state of each patient, reducing the frequency of false positive alarms without sacrificing sensitivity to true adverse patient states.

Current Support

Goal	Time Frame	Current Status	Requested Support	Requested Support Source(s)
Coordination	FY21	Currently supported by DAR-Research under RSI	CIVL Director 0.1 FTE	Continued support under Stanley Manne/Renewed RSI

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Technical Appendix

Types of Data

It's important to understand the types of data that can be collected from bedside monitors and devices and how different systems can store and use this data, as shown in Figure 1. Because of network performance limitations, some systems (such as Etiometry) can only store low frequency vitals, and not waveforms. Yet another type of data that is integrated through bedside monitors is *alarm* data. These are indicators of events in which physiological variables exceed thresholds or notices of data quality or equipment failure.

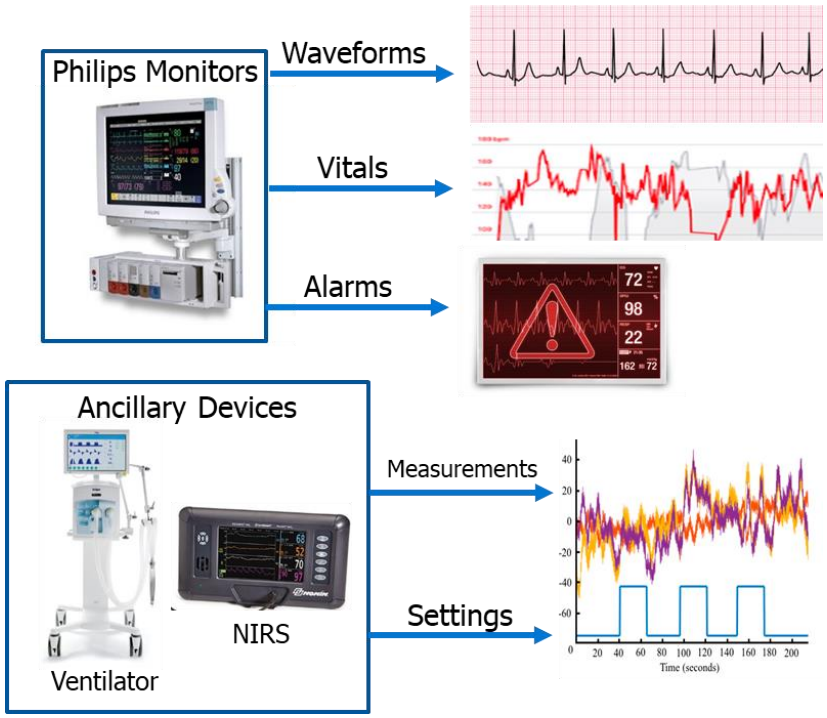

Figure 1 The fundamental data types from bedside monitors and devices. ***Waveforms*** *are high frequency sampled signals, such as EKG, directly from physiological sensors like skin surface electrodes or pressure transducers.* ***Vitals****, or* ***numerics****, are values like heart rate or systolic blood pressure that are derived from raw waveforms and typically sampled at lower frequencies (such as once a second or every 5 minutes).* ***Alarms*** *are indicators of signal quality issues or physiological values that are out of expected range. Though not traditionally interpreted as vitals, ancillary devices also produce numeric* ***measurements*** *that reflect the patient's physiological state. Devices may also relay high frequency waveform data as well as intervention* ***settings*** *(such as the commanded respiratory rate).*

Data archival systems have generally focused on storing waveform and numeric data that is available from a centralized beside monitor (such as Philips or GE), since that is governed by a single interface. Nonetheless, clinically important data can be derived from bedside devices that are less frequently u sed. Examples are ventilators and near-infrared spectrometers (NIRS). Since these *ancillary devices* are often provided by separate vendors, data integration has been much more difficult to standardize. Some can be connected through adaptor modules to our Philips monitors, but these connections have not typically

been used at Lurie. Other third-party integration vendors typically support connecting these devices through some sort of networking hub or tablet interface. When these devices are connected, they are potentially capable of generating waveform level data, such as continuous airway pressure, but are most often used for capturing *measurements* (cerebral oxygenation, for example) or device *settings* (such as the set ventilator rate).

Data from wireless and wearable sensors present another frontier in physiological precision medicine. In addition to freeing patients from cumbersome wired monitoring while in the hospital, as John Rogers' work has shown these technologies offer a range of completely novel sensing modalities. In addition, given the possibility of telemetric monitoring of outpatients (as in Dr. Carolyn Foster's work) there is a huge potential to anticipate and avoid hospitalizations for acute exacerbations diseases. Similarly, data from consumer wearables may provide a rich data source for patient monitoring if placed in the proper context of validated measures and embedded in an informatics infrastructure that can support them. This priority has been recognized by the institution as part of the Patient Reported Outcomes initiative.

Key Capabilities

Almost any conceivable application of bedside data for research, operations, or clinical decision support requires a certain minimal set of capabilities (Figure 2). By definition, such systems should be able to ingest and store data from bedside monitors. Even for minimal clinical use, vitals, waveforms and alarms should be made available from short-term storage for review (as is true for the clinical Philips Central Station, which allows data review for data up to a few days old). For the most advanced research applications, these data sets must be stored indefinitely at the highest resolution possible, with simple tools for retrieving historical data by patient and date/time range, for extracting cohort data sets for analysis in other tools and for applying custom analytic algorithms against the data. As Dr. Brady's research has shown, data from ancillary devices (such as NIRS and ventilators) is also essential to development of advance patient monitoring intelligence. For such applications it is essential that these devices be interfaced at the highest resolution available (e.g. waveforms), and that millisecond time stamp synchronization is maintained between these devices and others recorded from the same patient.

While a great deal can be accomplished with research analysis of historical data in retrospective cohorts, the promise of precision medicine as applied to physiological monitoring requires the ability to capture, process and display real-time data from bedside monitors and devices, all integrated with EHR data elements. This 'streaming analytics' capability is foundational for advanced clinical decision support, particular in critical and emergency care. A streaming analytics platform should provide a means to develop custom analytics and visualizations with reliable data flow and clinically relevant temporal precision.

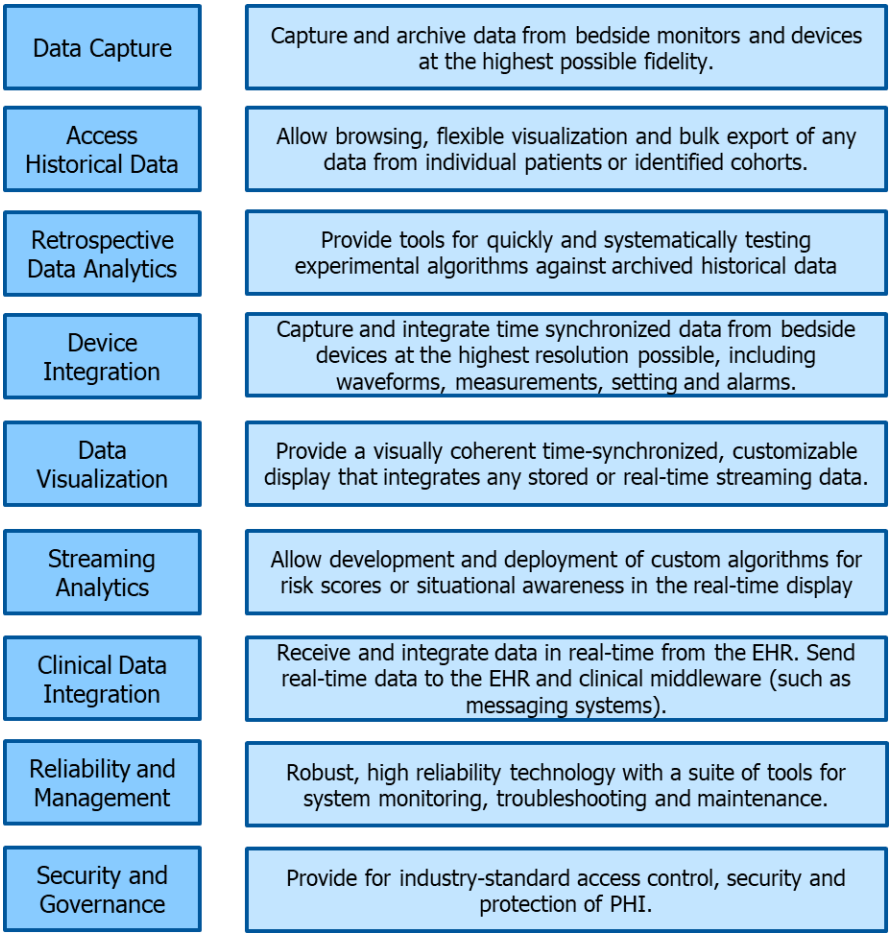

Figure 2 Key capabilities for bedside data archival and analytic systems.

Vendors and Products

BedMaster

The BedMaster system (sold by Excel Medical, recently acquired by HillRom) was first deployed in the PICU and CCU in 2012/2013. The system was later expanded to the NICU (and to twelve beds in Prentice) in support of the Pre-Vent grant. During the ICU expansion BedMaster licenses were pulled from the CCU (and redistributed to other floors) in anticipation of a new system to be installed there. The Excel-Medical/HillRom product line includes a system for capturing data from bedside ancillary devices which is called BedComm and a newer clinically marketed product called WAVE, but in practice we tend to use BedMaster to refer to all of their products.

Key Points

- BedMaster captures full waveform level data from sensors and devices connected to the Philips monitors along with vitals. Ancillary device data can be collected through BedComm, but that has not been extensively used.

- BedMaster is currently licensed for research uses only. They have encouraged clinical applications, but they have been vague about how those might be licensed and they have also not impressed us with their ability to deliver systems that are reliable enough for mission critical clinical applications.

Etiometry

Etiometry is a vendor that has bedside monitoring and predictive analytics display. The three specific products are the T3 Data Visualization platform, a physiological Risk Analytics Engine (with an FDA approved oxygenation model called the IDO2 Index and a historical data store called the Quality Improvement System.

Key Points

- Etiometry captures only low-resolution vitals with no waveform-level data.
- The only capability that unique to Etiometry is the IDO2 risk score. All other capabilities can be reproduced with Sickbay

Sickbay

Sickbay is a platform sold by Medical Informatics Corporation. It includes a variety of applications for visualizing and analyzing historical and streaming bedside data. It was recently deployed in the CCU and several of the cardiovascular procedure ORs. The MDADI committee has recently proposed introducing Sickbay into the remain ORs as part of replacement for the current system.

Bernoulli/Capsule

Historically, data from anesthesiology cart systems in the ORs have been ingested in the EHR for automatic posting of vitals data during surgeries. The original vendor (Bernoulli) has recently been purchased by Capsule, who have abandoned support for legacy devices (as of March 2021) and recommended a costly replacement. These systems are being replaced with Sickbay, which could continue to push vitals to the EHR while also allowing a much broader range of applications.