Pilot of an automated EHR adverse event monitoring system
PROSPECTUS FOR MASSACHUSETTS ACUTE CARE HOSPITALS

The opportunity

To implement a key action step of the _Roadmap to Health Care Safety for Massachusetts,_ the Betsy Lehman Center has engaged Pascal Metrics Inc. to pilot automated EHR safety monitoring in 6-8 Massachusetts acute care hospitals. Starting in October 2024, this 18-month pilot will test whether these systems enable and support sustained, significant improvements in safety outcomes across a diverse cohort of the state's hospitals.

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This prospectus introduces the pilot's goals, process, and expectations for participating hospitals. In April 2024, the Betsy Lehman Center will begin hosting a series of four online informational sessions open to any hospital interested in serving as a pilot site. These detailed interactive sessions are designed to anticipate and respond to questions hospitals may have about the potential benefits and conditions of participation.

Value of automated EHR safety event monitoring

Health care providers need timely, robust information to identify patient safety events and risks within their organizations and take action to prevent future harm. Though many hospitals have invested considerable resources in manual safety event reporting systems, these systems rely on staff and patients to "see something and then say something" and do not always yield the information that hospitals need to improve safety processes and outcomes.

Automated EHR safety event monitoring is a new but proven technology that can run in the background of any EHR and detect many more serious harm events than hospitals are identifying through current methods (see Appendix 2 for a sample of 100 event types). Based on peer-reviewed published evidence, these systems offer leaders, managers, and staff the timely and comprehensive information they need to promptly identify and respond to safety risks and events, while reducing the burden of manual reporting on frontline staff and patients.

Though early-adopter hospitals across the country have shown dramatic, sustained reductions in preventable harm events and liability claims — and significant returns on their investments — no Massachusetts hospital has implemented such a system to date.

This first-in-the-nation pilot

The Betsy Lehman Center is leading this first-in-the-nation pilot to implement an automated EHR safety event monitoring system in a diverse cohort of Massachusetts hospitals and evaluate its impact. To help guide this initiative, the Center has convened an Advisory Committee comprised of experts in patient

safety, continuous improvement systems, leadership, and change management (see Appendix 1 for a list of members).

The goals of the pilot are to demonstrate whether and how these systems could:

- Produce daily validated data on a wide range of safety events that hospitals can use to inform and power their existing improvement systems and activities;
- Help hospitals achieve significant and sustained improvements of patient outcomes by reducing preventable harm events;
- Ease the burden of manual reporting on frontline staff, while promoting a culture of safety and workforce well-being;
- Serve as a source of meaningful information on statewide patient safety events, risks, and trends; and
- Reduce the costs associated with preventable harm events at the individual hospital level (e.g., non-revenue generating services, liability claim expenses and payouts) and statewide (e.g., excess health insurance claims to commercial plans and MassHealth).

Over time, a successful pilot could be scaled to all Massachusetts hospitals and many ambulatory and long-term care settings, resulting in even greater cost savings and reductions in patient harm.

The Betsy Lehman Center has contracted with Pascal Metrics to bring automated EHR safety monitoring to 6-8 acute care hospitals that represent the diversity of Massachusetts hospitals. Pascal Metrics has worked with health systems for over 15 years and has implemented its automated event monitoring system in over 50 health systems and hospitals nationally. Its status as a federally-listed Patient Safety Organization governed by 42 U.S.C. § 299b-22 and 42 C.F.R. § 3.204 enables it to maintain the confidentiality of its findings and collaborative work with hospitals and health systems to improve patient safety and reduce risk.

The Pascal Metrics approach:

- Automates identification of patient harm events by integrating a hospital's EHR with a PSO-protected cloud service that leverages evidence-based, clinically validated triggers and cutting-edge information technology;
- Employs a remote team of trained physicians and nurses to validate adverse event outcomes and generate additional insight, preventing the reporting of false alarms to hospitals, relieving hospitals of those burdens, and making this technology-enabled method a mission-critical part of clinical operations; and
- Provides expert training, consultation, and support to hospitals to help them use this more accurate, timely, and actionable data stream to understand adverse events and trends and address underlying safety causes, factors, and risks — preventing future harm.

Roles and responsibilities

Betsy Lehman Center. The Center will:
- Procure and provide general oversight of the vendor (Pascal Metrics);
- Cover the costs of Pascal Metrics' services to the pilot hospitals;

- Conduct the hospital outreach and selection process in consultation with the Advisory Committee and Pascal Metrics;
- Facilitate a monthly learning collaborative for participating pilot hospitals;
- Receive monthly deidentified hospital level data from Pascal Metrics; and
- Participate in an independent evaluation of the pilot by an external research team and the publication of its findings.

Pascal Metrics. Pascal is contracted with the Betsy Lehman Center to:
- Technically integrate with pilot hospitals' EHRs its Virtual Patient Safety platform that uses automated triggers to scan every patient record daily to identify patient harm events;
- Stream data into a protected environment where trained physicians and nurses validate safety outcomes and generate other insights every 24 hours;
- Provide clinically validated adverse event outcomes analytics ("AE Outcomes") and other documentation to authorized hospital personnel who can drive concurrent intervention and high frequency cycles of improvement with accurate, timely, and actionable data;
- Provide individualized consultation services to help each pilot hospital understand the data and use it to inform and support their existing continuous improvement systems; and
- Confidentially share data and analytics with the Betsy Lehman Center and a third-party research team for evaluation purposes. Confidentiality will be assured through data sharing agreements between Pascal Metrics and each pilot hospital and between the Betsy Lehman Center and each pilot hospital.

Hospital participation

Pilot hospital eligibility and selection

All acute care hospitals in Massachusetts are eligible to apply for the pilot. A committee comprised of Betsy Lehman Center staff, members of the Advisory Committee, and Pascal Metrics will select a diverse cohort of 6-8 hospitals, using certain criteria to assess each interested hospital's readiness to participate. Considerations will include:

- Hospital executive leadership's support for and prospective level of engagement in the pilot;
- Hospital preparedness to follow through on its commitments during each phase of the pilot (see below), including availability of essential executive leadership, clinical leaders and managers, and IT staff;
- Hospital capacity to engage in safety improvement, including established systems for continuous improvement within a culture of safety;
- Hospital size, region, type, and EHR system; and
- Reasonable EHR implementation maturity (Pascal Metrics system can be integrated with any commercial EHR that conforms to industry standards).

Note: Hospitals that are transitioning to a new EHR (or that have plans to do so during the pilot period) are unlikely to qualify for the pilot. Hospitals that have recently implemented a new EHR will be assessed on a case-by-case basis.

Benefits to pilot hospitals

In addition to recognition for playing a leading role in a novel demonstration that could dramatically advance the field of health care safety, pilot hospitals will have the opportunity to:

- Receive free access to technology that yields accurate and timely information about safety events and risk trends that early-adopter hospitals have used to achieve rapid, significant, and sustained reductions in a wide range of harm events and impressive financial returns on investment;
- Improve readiness to meet EHR-based hospital harm measures and structural measures already being promulgated by CMS and expected to increase in number, as well as potential changes to national hospital ratings requirements (e.g., Leapfrog);
- Reduce the manual reporting burden on frontline staff;
- Improve patient experience and reduce legal liability and related costs by taking action while a patient is still receiving care in the hospital; and
- Participate in a learning collaborative with pilot hospitals across the state that are striving to embed and sustain safety improvement as a strategic priority.

Pilot hospital commitments

It is expected that each pilot hospital will:

1. Enter into a memorandum of understanding with the Betsy Lehman Center that defines the parties' respective commitments and responsibilities and addresses how the data and analyses will be shared and used;
2. Enter into a business agreement with Pascal Metrics that describes Pascal's services to the hospital, system implementation, and data use;
3. Collaborate with Pascal Metrics on integrating data feeds from the hospital's EHR to Pascal's PSO cloud service;
4. Integrate the data it receives from Pascal Metrics analytics into its current structures for advancing continuous improvement within a culture of safety (hospitals are *not* expected to implement a new or standardized improvement system for purposes of the pilot);
5. Conduct internal communication activities to inform staff about participation in the pilot;
6. Ensure that appropriate leaders and staff are available and prepared for each phase of the pilot, and that they engage with Pascal Metrics' clinical leaders, team, and data analytics as needed. This includes:
   - Designating a hospital champion with appropriate leadership capabilities to facilitate hospital engagement on the part of executives, quality and safety leaders, IT staff, and clinical teams;
   - Ensuring that executive leadership has access to the Pascal Metric's dashboard and receives regular reports on patient harm events;
   - Presenting pilot progress updates to the Board quality committee or full Board at least quarterly;

- o Designating a senior leader, safety and quality leader, and relevant managers to participate in monthly virtual meetings of a learning collaborative that will facilitate an exchange of information and ideas among the pilot hospitals, Pascal Metrics, and the Betsy Lehman Center;
7. Authorize Pascal Metrics to share deidentified hospital level-safety event data with the Betsy Lehman Center for the Center's use in understanding progress over the course of the pilot (data confidentiality will be maintained as described below);
8. Participate in pilot evaluation activities including key informant interviews and/or surveys to provide context on the continuous improvement methods, resources used, and lessons learned before, during and after the pilot; and
9. Agree that the Center may publish and communicate pilot evaluation results that use nonidentifiable aggregate data, including in academic journals. Confidentiality regarding individual pilot hospital experience will be maintained in any public communications or publications.

Confidentiality

Under Massachusetts law, M.G.L. c. 12C, section 15(e), information received by the Betsy Lehman Center is confidential. It is not public record and is not subject to subpoena or discovery or introduction into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law. This protection applies to the data that the Center will receive during the pilot.

Pascal Metrics is a Patient Safety Organization (PSO). Under federal law, 42 U.S.C. § 299b-22 and 42 C.F.R. § 3.204, the clinically validated adverse event outcomes based on real-time EHR data generated by Pascal is considered Patient Safety Work Product and is protected from disclosure.

Timeline
- Phase 1 activities March-Sept 2024
    - o Information sessions (Apr-May)
    - o Pilot hospital selection process (May-Jul)
    - o Pre-implementation activities to prepare selected hospitals for technical integration of software into their EHRs and for using the analytics (Aug-Sep)
    - o Baseline surveys or interviews for evaluation (Aug-Sep)

- Phase 2 activities Oct 2024-March 2026
    - o Software integration and data validation (Oct 2024-Mar 2025)
    - o Go-live (Mar 2025)
    - o Daily adverse event analytics posted to hospital dashboards (Mar 2025-Mar 2026)
    - o Pascal Metrics consultations with hospitals on applying the analytics to their safety improvement systems (as needed, starting bi-weekly and becoming less frequent as hospitals mature in their implementations) (Mar 2025-Mar 2026)
    - o Monthly deidentified hospital-level event data from Pascal to the Betsy Lehman Center (Mar 2025-Mar 2026)
    - o Monthly Learning Collaborative meetings (Mar 2025-Mar 2026)

- Post-pilot activities (Apr-Sep 2026)
  - Final evaluation activities
  - Betsy Lehman Center findings and recommendations
  - Academic publications
  - Broaden access to the technology to more hospitals and other clinical settings as appropriate

Information sessions (virtual)

Please attend the following online information sessions. Dates and registration information will be provided in follow-up communications and posted on the Betsy Lehman Center's website.

Session	Topics
1. About the pilot	- Goals and what to expect - Introduction to Pascal Metrics leadership and offerings
2. Analytics and improvement support	- Adverse event analytics - Applying data to safety improvement and risk reduction - Data sharing and confidentiality
3. Real-world experiences	Q&A with leaders of early adopter hospitals
4. Readiness and next steps	- Hospital readiness criteria - Hospital selection process and timeline

Advisory Committee members

Ivyruth Andreica, PharmD, BSN, FISMP	Medication Safety Consultant
David W. Bates, MD, MSc	Mass General Brigham
Maryanne Bombaugh, MD, MSc, MBA, CPE	Cape Cod Community Health Center
Ray Campbell, JD, MPA	Former Executive Director, Center for Health Information and Analysis; Instructor, Harvard T.H. Chan School of Public Health
Connie Crowley-Ganser, MS, RN	Quality Health Care Strategies
Patricia Folcarelli, RN, MA, PhD	Senior Vice President for Patient Care Services and Chief Nursing Officer, Beth Israel Deaconess Medical Center
Tejal Gandhi, MD, MPH, CPPS	Chief Safety and Transformation Officer, Press Ganey
Paula Griswold, MS	Executive Director, MA Coalition for the Prevention of Medical Errors
Regina M. Hoffman, MBA, RN	Executive Director, Pennsylvania Patient Safety Authority
Kim Hollon	Retired President & CEO, Signature Healthcare Brockton
Jon Kingsdale, PhD	Brown University
Erin Long, MSN, RN	Nurse Analyst, Quality and Patient Safety Division, Massachusetts Board of Registration in Medicine
Patricia McGaffigan MS, RN, CPPS	Vice President, Institute for Healthcare Improvement; President, Certification Board for Professionals in Patient Safety
Elizabeth Mort, MD, MPH	Former Senior Vice President of Quality and Safety, Massachusetts General Hospital and Mass General Physicians Organization; Primary care physician, Beacon Hill Primary Care
Kiame Mahaniah, MD, MBA	Undersecretary for Health, Executive Office of Health and Human Services
Patricia Noga, PhD, RN, MBA, NEA-BC, FAAN	Vice President, Clinical Affairs, Massachusetts Health & Hospital Association
Kristin O'Reilly, RN, BSN, MPH	Program Director for Patient Safety, CRICO
Luke Sato, MD	Senior Vice President and Chief Medical Officer, CRICO
Lakshman Swamy, MD, MBA	Medical Director of Payment & Care Delivery Innovation, MassHealth

100 Sample Adverse Event Types Identified by the Pascal Virtual Patient Safety Solution

Illustrative and Not Exhaustive

Venous Thrombolytic Events (VTE)	Post-operative Anastomotic complication	Retained tissue	Mental status change
Fall with injury	Catheter-related urinary retention	Preterm delivery of an infant	Neurological complication related to surgery or procedure
Post-operative / Post-procedure pain	Premature extubation causing respiratory failure	Surgical Complications	Missed diagnosis
Respiratory complication related to medication	Anesthetic airway mgmt. issue	Medication-related constipation	Neonatal birth injury
Fall without injury	Epidural/Spinal-related event	Pressure Ulcers	Post-operative wound dehiscence
3rd degree lacerations	Clostridium difficile medication associated infection	Hypertension in preg incl preeclampsia	Skin tear, abrasion, or other breakdown
Return to surgery	Neurological complication related to medication	Neurological complication	Sepsis-related event
Maternal Hypertension	Complications related to peripheral venous puncture	Acute renal injury	Constipation / Obstipation
IV infiltrate	Intravenous (IV) volume overload	Hypotension	Respiratory infection (non-ventilator associated)
Blood therapeutics	Patient deterioration	Iatrogenic pneumothorax	Newborn metabolic acidosis
Duplicate discharge diet order	HIT-related misconfiguration harm	Respiratory complications	HIT-related malfunction harm
CAUTI-CLABSI-C Diff Composite	Transfusion-related event	Hyperbilirubinemia	Obstetrical hemorrhage
Hypoglycemia	Neonatal resuscitation or injury	Intubation-related event	Med-related allergic reaction
Post-operative / Post-procedure urinary retention	Central line associated BSI	Cardiac complications related to surgery or procedure	Equipment-related event
Aspiration pneumonia	Surgical Site Infection	Anesthetic induction issue	Percutaneous Coronary Interventions
Medication-related coag	Post-operative / Post-procedure ileus / SBO	Catheter associated urinary tract infection	Maternal hypotension requiring treatment
Cardiac Arrest	Equipment failure/malfunction	Unplanned Return to Surgery	Pressure Injuries
Abnormal bleeding following surgery	O-E sepsis mortality	Maternal infection/sepsis	Electrolyte imbalance
Eclampsia	Cardiac complications	Post-operative wound infection	Removal, retained foreign body
Medication-related toxicity	7-day readmissions	Medication-related bleeding	Ventilator-associated pneumonia
Neonatal events	Gastrointestinal hemorrhage	Oversedation	Surgical Site Infections
Stroke	Placental Abruption	Removal, injury or repair of organ	Delivery complication
Healthcare-Associated Clostridium Difficile Infection	Misread of radiology study	Post-op fever	Altered Nutrition
Unexpected transfer to ICU	Postpartum hemorrhage	Complications related to peripheral arterial puncture	Respiratory complications related to surgery or procedure
Retained placenta	Preeclampsia with severe features	4th degree lacerations	Missed diagnosis, oncology