



Virtual Patient Safety (VPS) Solution

Frequently Asked Questions

The questions and answers provided below are not exhaustive. Pascal Metrics and the Betsy Lehman Center are available to meet with individual hospitals and systems to provide further information.

- 1. Is Pascal Metrics' solution being used in hospitals and health systems, or is it still in developmental or production stage? If this is a solution being used to support client operations, how many hospitals are actively using it?**
 - 1.1. The Pascal Virtual Patient Safety (VPS) solution, comprised of both software and services, is a production stage system that is fully operational and in use to support mission critical operations 7 days a week in hospitals across the country. It is not an academic research project or a commercial R&D initiative in testing.
 - 1.2. Pascal has successfully scaled VPS across dozens of hospitals, including health systems with 140-, 144-, and 220-hospital footprints. We have not deployed in a single client across more than 100 hospitals as of yet, but our solution both technically and operationally has been shown to be capable of doing so.
 - 1.3. Pascal has successfully deployed in various settings including small, very large, community, academic medical center-anchored, pediatric, and government hospitals and health systems.

- 2. Pascal states that an automated trigger system can detect as much as 10x the number of serious safety events that voluntary event reporting does. What is the difference between a trigger and an adverse event? How many event notifications should we expect to receive per day/week?**
 - 2.1. Clinical triggers are data elements in the medical record that indicate a potential adverse event *may* have occurred. They are used to identify potential harm suffered by a specific patient in a specific moment of time that prompts and requires further investigation. Therefore, a trigger points to potential harm but is not indicative of harm per se.
 - 2.2. An adverse event, or specifically a clinically validated adverse event outcome using EHR or health IT data ("AE Outcomes"), constitutes an actual patient harm suffered by a patient. An AE Outcome is harm suffered by a specific patient which is defined with a methodology rooted in sound epidemiology and classified according to event type, severity, location, and so on.
 - 2.3. Pascal can provide an estimate of how many notifications or escalations a specific hospital should expect based on some key variables. That said, VPS avoids overwhelming clinicians because it only escalates certain adverse events that clinical judgment deems critical for caregiver awareness. The rest of the AE Outcomes and related analytics are available on the hospital's dashboard for further analysis to see trends and inform improvement efforts, but don't trigger a report. This is the benefit of the distinction between background surveillance and foreground surveillance, as well as the importance of both.



What is the overlap of events commonly identified through hospitals' voluntary event reporting systems and those measured by Pascal VPS?

- 2.4. There is overlap, but Pascal has observed that VPS regularly identifies 10x the level of serious harm (as defined as NCC-MERP F-I) as event reporting even in high reporting hospitals with positive safety cultures. See the article "Patient Harm Events and Associated Cost Outcomes Reported to a Patient Safety Organization" for a real-world example.¹
- 2.5. One of the reasons why hospitals deploy automated event monitoring is the lack of visibility of serious harm which benefits from being measured. This is useful for those hospitals which aspire to be high reliability organizations or on a path to zero harm. This also gives greater insight into serious safety event rates as an indicator of high performance.
- 2.6. The near real-time nature of automated monitoring also means that hospitals are aware of serious safety events more quickly than from voluntary event reporting, including those occurring while the patient is still receiving care and can be ameliorated or avoided.
- 2.7. There is no requirement for a client to replace or materially change how it conducts Voluntary Event Reporting (VER) with its existing software and workflow. Clients run VPS and their VER systems in parallel in the Demonstration Stage to make sure it works. Once a client validates the ability of VPS to identify up to 10 times the level of serious patient harm — defined as NCC-MERP F through I — as compared to the patient harm identified by existing event reporting systems in hospitals even with positive reporting cultures, they embrace the strategy of VPS being the foundational source of monitoring, measurement, and management and augment that with pre-existing and enhanced event reporting, a valuable source of learning.

3. Our hospital has a very strong culture of safety reporting. How would adopting this automated approach benefit us?

- 3.1. Please see Section 2.4 above. Even hospitals with strong cultures of safety reporting validate that Pascal VPS identifies 10x the level of serious harm (as defined as NCC-MERP F-I) as found by voluntary event reporting.
- 3.2. VPS supports and enhances safety culture by improving the quality and strength of safety event data that feeds improvement efforts. With enhanced data, improvement and safety culture get better through more learning and greater precision of efforts. Overall, there is a role for timely AE Outcomes to play in understanding, improving, and protecting safety culture. Safety culture is foundational, but hospitals will achieve only limited outcomes improvement without the use of more accurate, timely, and actionable AE Outcomes.²
- 3.3. All hospitals have limited resources. Hospitals embracing VPS find that understanding far better how every patient is suffering from harm (or not) across its population enables it to optimize resource allocation across the patient population being served. A software solution that identifies the harms maximizes the limited resources in hospitals by moving away from suboptimal data systems that rely on intensive human capital to identify harms. Human capital

¹ Miller, S. and Stockwell, D.C., 2023. [Patient Harm Events and Associated Cost Outcomes Reported to a Patient Safety Organization](#). *Journal of Patient Safety*, pp.10-1097.

² Aspects of this relationship are also borne out in the literature, showing an inverse relationship between all-cause harm with respect to safety culture, employee engagement, and patient experience. See for instance Sammer, Christine et al. "Examining the Relationship of an All-Cause Harm Patient Safety Measure and Critical Performance Measures at the Frontline of Care." *Journal of patient safety* vol. 16,1 (2020): 110-116.



can then be spent on improvement activities.

- 3.4. Clients find that, once VPS is fully implemented and subsequent improvement activities commence, being able to see adverse events or risk identified in minutes, hours, or days and then acted upon to improve care invigorates front-line staff (i.e., as compared to traditional improvement cycles that may take weeks, months, or years). It helps to reinforce that all staff are working on safety, from front-line to administrative staff, and doing so every shift, every day. All are working to find safety events, speaking the same “language” of harm, and working diligently to ameliorate and avoid these events.

4. Does the approach tend to identify certain types of harm events more than others? What are some examples of adverse events that the system detects, including those not typically identified through event reporting systems?

- 4.1. The breadth (i.e., adverse event types) and depth (i.e., finer-grained adverse event sub-types) of patient harm that the Pascal Virtual Patient Safety (VPS) solution can identify is extensive, comprising hundreds of adverse events. See a sample of 100 adverse events that VPS detects in Appendix 1 of the pilot Prospectus.
- 4.2. Adverse events such as hypoglycemic, hyperglycemic, and over-sedation harm are captured when implementing at clients — despite significant pre-existing initiatives, technology, and investments — and VPS also is capable of capturing more infrequent harms such as health IT-related harms (e.g., diet order misconfigured in the EHR resulting in readmission in the ED) as well as harm caused by well-intentioned evidence-based implementation of order sets that simply are never proactively measured for safety.

5. How will our data be stored and used? Who will have access to it?

- 5.1. Pascal stores the data provided in our PSO-protected cloud service. Only the Pascal team has access to your identified patient data.

6. How does Pascal access the EHR data?

- 6.1. Pascal conducts a one-time technical Integration. Hospital EHR implementation data feeds are integrated into Pascal’s cloud-based PRIME (Patient Real-time Interoperable Metrics Engine) infrastructure. The primary point of contact is a health system or hospital’s IT manager as well as a one-time set-up process with a network specialist to help establish connectivity to our secure VPN; an integration engineer to point HL7 messages to our system; and an application specific interface analyst(s) to assist in the data validation process.
- 6.2. As long as the health system is able to provide the requisite feeds in HL7 (and sometimes with supplementary flat files for e.g. a non-ADT feed) and has requisite EHR documentation (e.g. nursing notes) — which Epic, Cerner, and most commercial EHR vendor implementations include — then a health system’s management and infrastructure is “ready” to measure patient harm. The requisite feeds for Pascal’s cloud-based PRIME (Patient Real-time Interoperable Metrics Engine) infrastructure are ADT, Lab, Medication, eMAR, Nursing, Surgery, Radiology, Microbiology, and text notes (e.g., operative notes, discharge summary, progress notes, etc.) as well as admin and billing data.



7. If a hospital or health system wishes to continue with VPS after the pilot, how is the pricing calculated?

- 7.1. The pricing is calculated based on a ROI model delivering 3x-5x annual ROI to the health system client. For example, if a health system spends \$800,000 in annual subscription fees, the overall benefit is at least \$3.2M per year and ROI to the health system is \$2.4M, or 3x. If a health system spends \$3,000,000 in annual subscription fees, the overall benefit is at least \$12M per year and ROI to the health system is \$9M, or 3x. The primary ROI model starts with patient safety only; for example, the 3x ROI referenced above excludes value to risk management and revenue cycle.
- 7.2. The patient safety ROI is based on the measurement and reduction of patient harm which has been validated to generate excessive length of stay (XLOS) by multiple peer reviewed articles and real-world evidence. This XLOS-related cost reduction patient safety business model works as follows:

[Total Number of Annual Admissions* x Total Cost of Harm per Patient** x Expected Annual Rate of Patient Harm*** x Expected Annual Harm Reduction Rate***] - [Total Pascal VPS Annual Subscription Price*]

divided by

[Total Pascal VPS Annual Subscription Price*]

* This is factual data provided by the subject hospital or health system

** Based on real world data financially validated and presented at scientific conferences and consistent with peer-reviewed evidence

*** Based on real world data clinically validated by health systems and consistent with peer-reviewed evidence