CLARITY

PSO

A Patient Safety Organization

THE PSO OPPORTUNITY
2017 Report to Healthcare Providers

www.claritypso.com

Patient Safety – An Applied Science

Many scientists will tell you it takes a long time to infuse good research into common practice, and in healthcare this reality is evident across nearly every specialty. Healthcare delivery is incredibly complex, and sometimes what may seem like even the simplest of interventions requires repeated testing and acknowledgement. When this is applied to Patient Safety we know that serial testing is essential to ensuring that safety comes first – because safety always comes first!

In previous Clarity PSO Reports, we've carefully mapped out the foundations of the PSO program, what it is, what it does, and how providers can benefit from working with a federally listed PSO. With this report we'd like to share how we put our learnings into practice for our clients every day, and how our recommendations impact the culture behind their healthcare delivery models. In this report we will highlight:

- The State of the National PSO Program Today
    - o History
    - o National Standards and Reporting
    - o Legal Issues
- Quality/Safety Improvement from the Provider Perspective
    - o Case Studies from the Front Lines
- The Future of Patient Safety
    - o Safety Culture
    - o Where the PSO Program is Headed

What is a Patient Safety Organization?

By way of introduction to this report, PSOs are the product of the Patient Safety and Quality Improvement Act of 2005 (PSQIA). This Act called for the creation of entities (PSOs) to help healthcare providers in assessing and improving patient safety outcomes in the U.S. healthcare delivery system. The statutory provisions were designed to encourage all licensed providers to collect and report patient safety and quality information to a federally listed PSO. In return, all data reported to the PSO are protected as privileged and confidential.

A PSO creates a learning lab for healthcare providers and allows them to participate in patient safety activities (PSAs) and share sensitive information without the fear of liability. The protected information, which is referred to as Patient Safety Work Product (PSWP), includes any written or oral statements, data, reports, analyses, etc. that are developed for reporting to a PSO. The ability to examine PSWP and conduct PSAs gives healthcare providers the tools they need to reduce patient safety errors and improve healthcare outcomes.

Timeline and Milestones for the PSO National Program and Clarity PSO

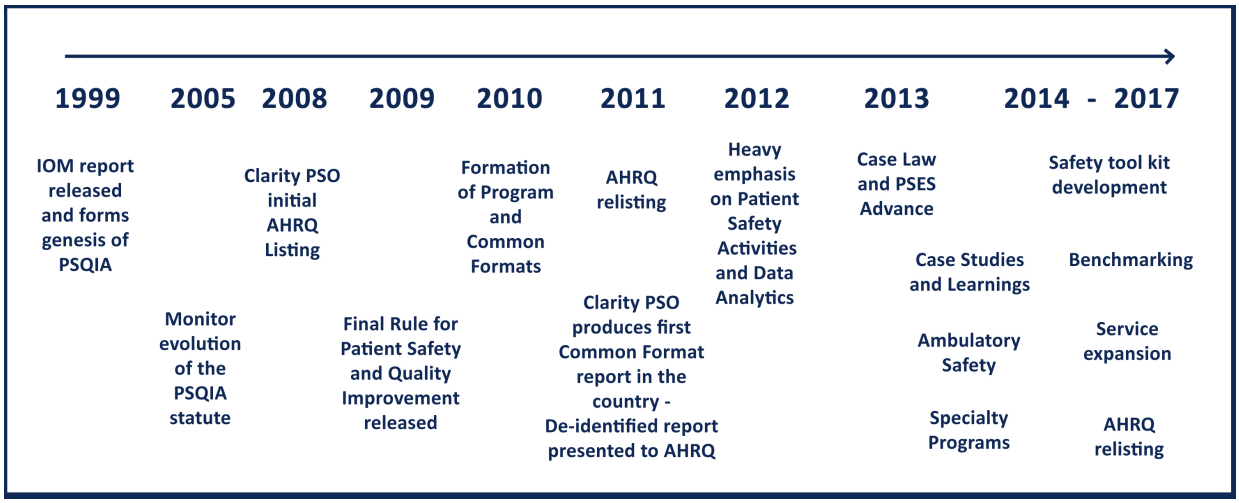

Figure 1: PSO Timeline

PSO History

The topic of patient safety really took off after the release of the IOM report, To Err Is Human, in 1999, which sent the industry scrambling to identify where and why there might be gaps in the self-regulation of medical errors. The focus immediately went to the reporting of those errors as a means of analyzing their pathways and ultimately fixing the underlying problems. Unfortunately, with mistakes come the potential for claims and expensive litigation. The response by healthcare institutions has often been that mistakes must be due to the person or healthcare provider who was involved in the patient's care. This has led to a punitive environment where reporting is tacitly discouraged due to hesitation and a fear of retribution on the part of the reporter. In such an environment, there is no incentive to learn from and fix our problems.

When the PSO Program was conceived, it was clear that the historically punitive reporting culture had led to a chronic lack of data about errors in healthcare delivery. Without any incentive to report errors, how are we to learn? There must exist an environment that supports reporting as part of its underlying culture.

Prior to the passage of the Patient Safety and Quality Improvement Act (PSQIA), there was little national focus on patient safety and error prevention. Some hospitals did do some transparent reporting, mostly as it relates to specific state requirements, which included some protections to encourage reporting. But there was no national standard and there were no federal protections. The PSQIA laid the groundwork for providers to report information in a secure and safe manner, with the primary aim of improving quality and safety of care delivery. The theory being: If we remove the fear of litigation and punitive measures, we encourage transparent reporting, thus giving us the data to teach us how to make healthcare safer.

The Core Work of PSOs

The job of a PSO is to work with its client-providers to receive and share sensitive information about the quality and safety of their care delivery, and to implement changes based on their findings. In turn, the information reported by the provider to the PSO is eligible for strong federal privilege to protect it from discovery in the event of a medical malpractice case and confidentiality protections, so long as the information is handled properly.[1,2,3]

In no uncertain terms, the PSQIA statute, and subsequently the PSO program itself, were designed to support the absolute need for a safety culture. But to encourage this, the privileged protections to shared patient safety data must hold up in the courts. To date, there are not an abundance of court cases (and no federal cases) where the challenges have been asserted, but those cases that have been brought, when viewed in the aggregate, begin to paint a picture of how those protections can hold up.

Clarity PSO feels strongly that providers must "Protect your protections." It refers to the idea that in order to best protect yourself, you must make sure all data you are sharing are submitted in accordance with the PSQIA. Clarity PSO works closely with our clients to ensure that their participation is structured is this way so that they can protect their protections.

The following are examples of some of our patient safety activities, which take the form of clinical, operational and even cost analysis of care delivery:

Near-miss Reporting	In-camera Patient Safety Collaborative	Long Term Care Reporting
Radiology Mis-read Analysis	Policy/Procedure Review and Manual Creation	Pediatric Dialysis Standards
Ambulatory Safety Program	Infection Prevention Project Collaborative	Fall Prevention Deep Dive
Behavioral Health Event Analysis	AMA Event Analysis	HIT-related Event Analysis
Nursing Peer Review	Moderate Sedation	Medication Error Deep Dive

1. Patient Safety and Quality Improvement Act of 2005. Public Law 109-41-July 29, 2005 at 42 U.S.C 299 et seq.
2. National Academy of Sciences: Institute of Medicine Report. To Err is Human: Building a Safer Health System. November, 1999.
3. Federal Register. Department of Health and Human Services: Patient Safety and Quality Improvement Final Rule: 42 CFR Part 3.

Understanding the framework under which care is delivered is the first step to building an effective safety program. With a good program in place, we all face the same underlying issues and challenges with error detection and prevention, regardless of the complexity or locus of care.

It is seldom the individual person that is the true factor in a failed process. Typically it is the process itself that is broken. The better we recognize how to layer our defenses, the better we are able to mitigate the errors that find their way through the holes in our systems[4]. By focusing on process and systemic fixes rather than personal blame, we begin creating an environment that supports a culture of safety, thus aligning ourselves with the true intent of the PSO program, and working toward a future free of preventable errors and harm.

Though we have a lot of work to do to get to a consistent and national Safe Culture in Healthcare, we have the conceptual framework for how it could happen. Thought leaders such as Sidney Dekker[5,6] point to the key elements of this cultural transformation. Through his work, in part, he essentially points out that it takes an entire organization to move its culture, and that such an endeavor must be grounded in three things:

Culture of Safety: Allows the front lines to step forward and tell us when things go wrong.

Culture of Learning: Eliminates finger-pointing when an error is made.

Culture of Justice: Once the first two are accomplished, the energy and efforts of the organization can be set around mobilizing the resources to build better processes, thus protecting our patients as well as our providers.

Figure 2: A Safe Culture

Common Formats

The Agency for Healthcare Research and Quality (AHRQ), which oversees the PSQIA and Patient Safety Organizations, created a set of reporting standards and templates called Common Formats, and Clarity PSO was an early adopter and encouraged our clients to adopt them as well. The power of Common Format reporting is the power of shared data. By standardizing providers' reporting parameters, we can learn from the data of one provider and apply it for the good of all providers. Clarity PSO was the first national PSO to demonstrate the use of Common Formats in aggregate form, and we continue to advance the learning that can be derived from such analysis, as you'll see in the following case studies.

4. Reason, J. Managing the Risks of Organizational Accidents. 1997. Ashgate Publishing Co.: VT.
5. Dekker, S. Just Culture: Balancing Safety and Accountability. 2012. Ashgate Publishing Co.: VT.
6. Dekker, S. The Field Guide to Understanding Human Error. 2014. Ashgate Publishing Co.: VT.

Case Study #1: Patient Identification and Medications – "Outside the Silo"

The figures below depict how one of our PSO client-providers collects patient identification information in relation to the medication administration process.

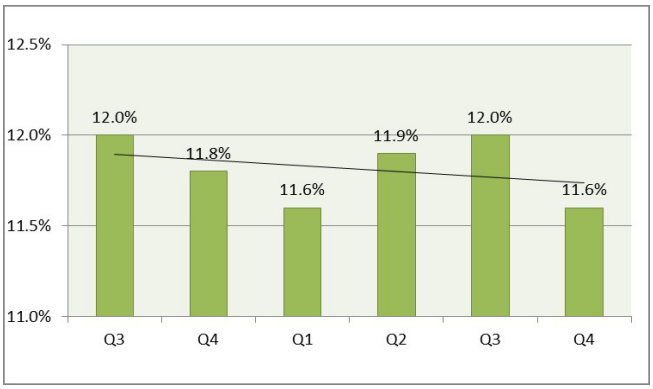

Figure 3A: Data in Silo

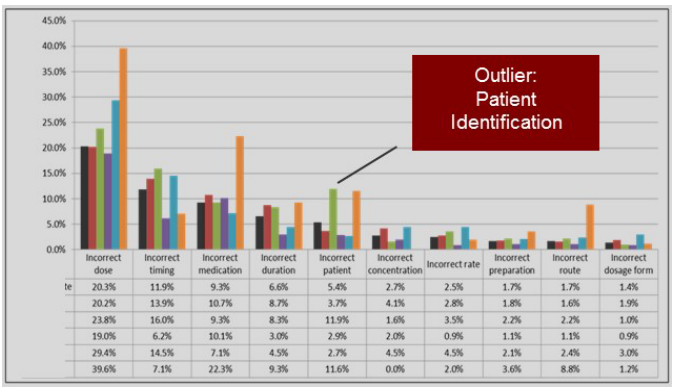

Figure 3B: Data in Context

The prevailing trend line in Figure 3A above indicates that this provider has been improving their recognition of patient identification issues, thus reducing errors with respect to medication administration over time. However, the data are being viewed in a "silo," lacking any context for what constitutes an average number of such errors at other providers. The graph in Figure 3B above compares this health system to other systems of similar size and function. The individual provider is now seen as an outlier, despite their improvements. In fact, this provider was still 2.5 times more likely to have medication errors associated with patient identification than similar providers.

Our finding prompted a series of questions that ultimately led to a systematic evaluation of the patient identification processes in place. The investigation revealed a number of deficits, including: loose and inconsistent policies; poor accountability for following department procedures (including IT/bar coding shortcuts that created unsafe conditions); and some general safety culture concerns.

Our interventions included the following:

- Proactive risk assessments of individual departments
- Identification of champions within the organization that could help with buy-in and overall awareness
- Revision of standards for patient identification, created in conjunction with staff
- New rollout of patient identification processes

After a period of time the data were extracted again, but this time we took a wider view, looking at all harm events rather than just medication events. The results indicated a significant reduction in harmful events as the organization moved forward. This is the power of data aggregation with a PSO. We began looking at just one event type, but the knowledge we gained and the interventions we adopted have led to an organization-wide safety awareness that has demonstrably shown to make patients safer. (See graph below).

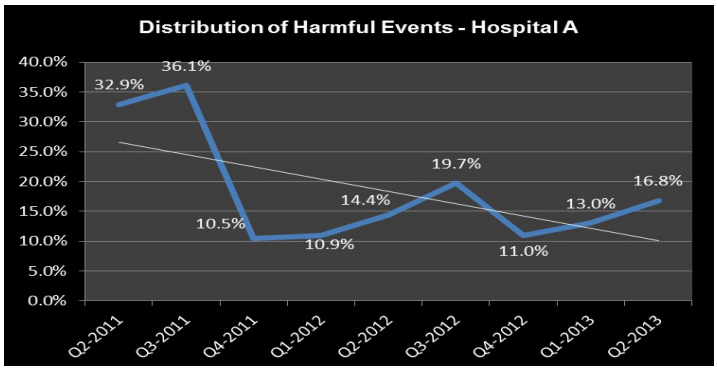

Figure 4: Decreasing percentage of harmful events at Hospital A

Case Study #2: Medication Screening – Falls and Ativan

As Common Formats are increasingly used and the base of data continues to grow, we start to see how the power of the data is magnified over time. In this instance, the "Falls" Common Format reporting template has evolved to include medication information.

Notice that industry-wide we have been able to identify specific medications that contribute significantly to instances of falls. Ativan (antianxiety medication) stands out as a drug that is particularly common, prescribed for a wide variety of reasons, and found throughout a large number of patient populations. Based on recommendations from Clarity PSO, one of our providers reviewed their use of Ativan and refined their prescription and administration of Ativan across all facilities. The result has been a more controlled use of Ativan, including limiting EMR drug choice and dose options for a given patient, which has aided in clinical decision support.

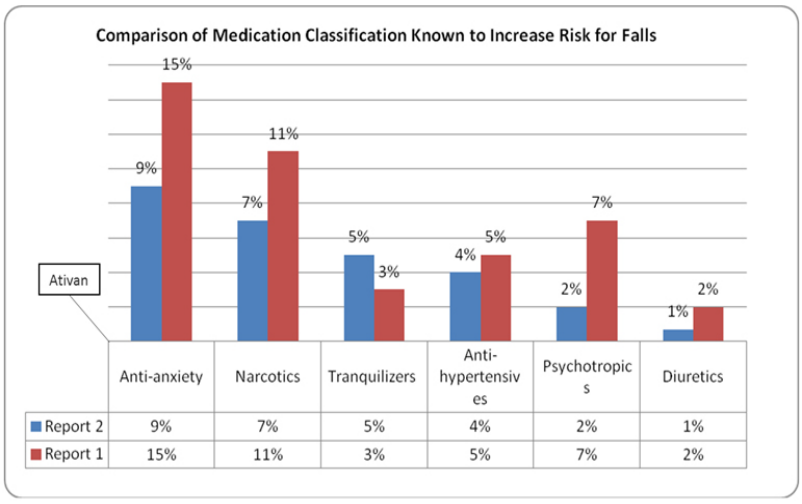

Figure 5: Comparison of medication classifications known to increase risk for falls

Case Study #3: Better Reporting in Obstetrics

Creating sound processes such as safety event reporting can often require numerous attempts and iterations to uncover the right questions that will get you the relevant data needed for analysis. This can be especially taxing for specialty providers, physician groups, and other ambulatory providers which tend to have fewer resources, less time, and less attention to focus solely on safety management. The most common way to refine reporting methodology is to first collect data, then analyze the data for meaningfulness, then go back to the reporting structure and adjust it so that the data coming back allow for more actionable results. Below depicts a workflow re-creation using an electronic event reporting module for obstetrics care. Since this is an ambulatory setting, the current Common Formats only loosely applied. Despite that, the PSO and provider were able to create a robust reporting platform.

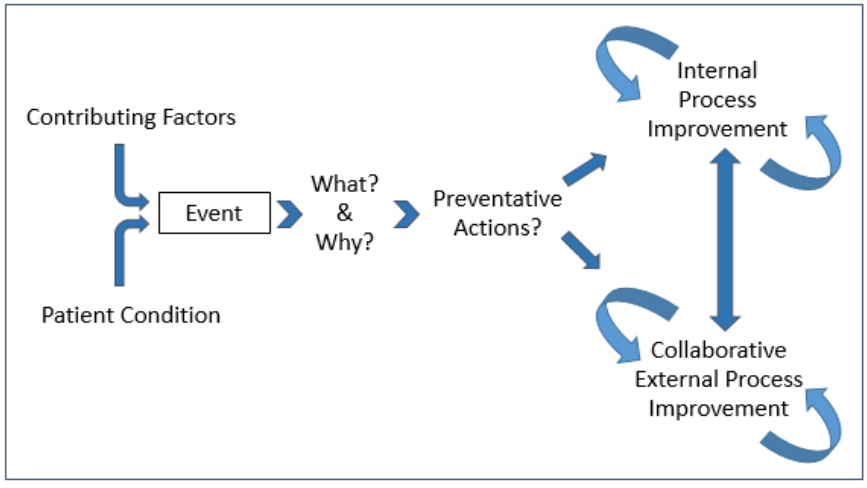

Figure 6: Workflow for continuous learning and improvement from events reported

Case Study #4: Utilizing Aggregate Reports for Your Own Learning

The clinical operations staff of Clarity PSO run a specialty program on behalf of a statewide Critical Access Hospital alliance, whereby we provide comparative benchmarks and specialty-specific analysis and recommendations to our client, and those are then used for the betterment of every provider in the group. We then engage each member provider to determine how they are using the reports within their organization to promote safety. The figure to the right describes a process we created with one of our client-providers to help guide organizations in how to break down reports and isolate those ideas which are most likely to yield real and positive change.

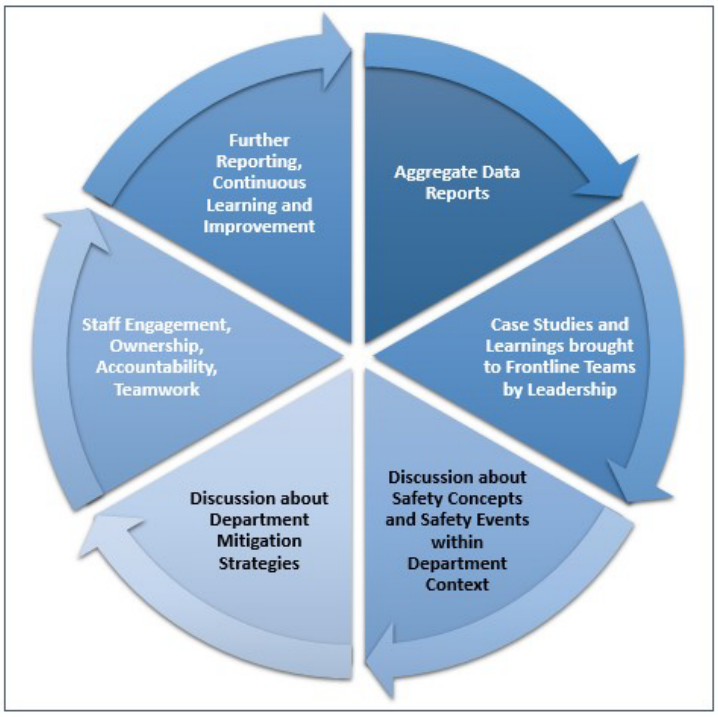

Figure 7: Cycle of Improvement and Learning from Aggregate Data Reports

As mentioned previously, one of the greatest benefits of reporting to a PSO is the ability to evaluate how you compare to similar providers. Once the comparative analysis is done by the PSO, the provider can evaluate how applicable a particular comparable is to its operations. PSOs can also help with respect to how to interpret the data and what sort of vetting process to use to determine the extent to which the data are relevant to process improvement.

The Future of PSOs

As previously discussed, the protections to patient safety data reported to a PSO are still in the throes of interpretation by the courts. But if you look closely at the cases thus far, and we as the PSO industry collectively make sure that providers continue focusing on the rigorous analysis of the data, then it is evident that this is really where the core of the PSO participation benefits exist and where much of the protections are likely to be upheld regardless of care setting.

Meanwhile, the analytical work of PSOs has already significantly advanced patient safety across the country, and will continue to provide us with insights that lead to changes in our care delivery models that help make patients safer than ever before. In our view, there are two important areas where the future of PSOs' analytical work should be centered:

Reported Data and Common Formats

Currently, the bulk of events submitted to PSOs consists of hospital forms, which are based on 1:1 event reporting (meaning one report submitted for one safety event). Through 2016, AHRQ has received a little over 310,000 of these reports. Going forward there will be a shift to the Surveillance Common Formats. These are intended to go beyond the individual event and allow us to look at more of a population-based analysis. PSOs will look to create rate evaluations across different sectors. This is already being done at a few individual PSOs, including Clarity PSO, but has not been reliably adopted nationally. With continued focus, we can begin to identify national error rates for various sectors of care delivery, allowing for broad-based industry safety improvement.

Understanding "Big Data"

Many of us have heard about and are trying to figure out what "Big Data" means in healthcare. Quite simply, data are coming from myriad different data sources in essentially every healthcare organization. This includes EMR and other clinical data, or safety event data, or Root Cause Analysis data, or voluntary and mandatory reporting data, just to name a few. So much of this information is still as yet "unharnessed" for the purposes of learning. However, efforts to link sources (such as EMR information with safety information) are indeed underway. One place where this is being done is in the Quality and Safety Reporting System (QSRS). The QSRS uses methodologies such as Natural Language Processing and clinical algorithms to try to get at what is commonly called predictive analytics or predictive modeling. Without taking a big picture view of this already complex environment, we will continue to miss opportunities to make our healthcare system as safe as it can be.

The Time is Now!

Clarity PSO is proud of the work we do on behalf of healthcare providers across the country. We believe that the concept behind the program has been proven, and that with the emergence of new healthcare configurations and new payment structures based on the quality of care delivered, the trajectory to create even greater benefits is steep and accelerating. The creation of the PSQIA paved the way for all providers to have a true learning laboratory to investigate harm and the potential for harm, and to promote interactions that can change the entire safety picture for improved patient outcomes.

The benefits of contracting with a PSO have come into focus. Get the most out of your existing resources by focusing attention on the areas where the data suggest it is needed most. Increase knowledge sharing and awareness building in a safe place protected from discovery. Take a system-wide look at events, accelerate decision making and support sustainable change over the long term. Enhance your culture of safety and watch it spread throughout your organization.

By working with Clarity PSO, healthcare providers have the power to move from repeat errors to a more predictive modeling process that can determine where the potential for harm exists and can be mitigated. We embrace our role as a part of this exciting movement, partnering with providers across the country to continuously foster excellence in patient care and safety in all healthcare delivery settings.

Advantages of Working with Clarity PSO

- Consultative process designed to allow the PSO to adapt to your organizational processes
- "Protect Your Protections" on-boarding process
- Resource extension of your own quality and patient safety efforts
- Focus on the continuum of care across expanding healthcare organizations
- Access to our Healthcare Advisory Council, a nationally recognized group of clinical and patient safety experts
- Patient safety activities tailored to your organization's needs
- Common Format Reporting for standardized benchmarking of clinical areas
- Experience with many facets of healthcare delivery, bringing a broad view to how patient safety and healthcare quality are addressed by various types of healthcare providers

About Clarity PSO

Clarity PSO is a component PSO and independent operating division of Clarity Group, Inc., one of the nation's leading healthcare professional liability risk management organizations. We listed as P0015 with the U.S. Department of Health and Human Services (HHS), Agency for Healthcare Research and Quality (AHRQ) on November 18, 2008, and relisted for the second consecutive three-year term through November 2017. Clarity PSO offers healthcare providers a full range of solutions for increasing patient safety, including analytical benchmarking, risk-quality-safety resources and systems development. The Clarity PSO team is dedicated to helping healthcare providers of all kinds mitigate risk while improving the quality of care.

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