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*Toolkit for Establishing PSO-based Network-Level Evaluation of Clinical Practices*

*Steps, Lessons Learned and Considerations*

**Target Population**

The target population applicable to the development of this toolkit is licensed providers who practice at more than one separately licensed facility within a health care network. The initial target population for the pilot is surgeons performing bariatric surgery at two separately licensed hospitals. However, the process described has relevance for all providers and services that might be shared between affiliated institutions.

**Safety Risk Being Addressed**

Like other CRICO institutions, BIDMC is the corporate owner of several community hospitals that remain separately licensed. BIDMC is moving rapidly to integrate services across this growing system, and there is now shared practice among academic departments. Numerous providers split their practice between two or more BIDMC network affiliates. However, as the institutions are separately licensed, pathways that allow for practice evaluation across institutions in a manner that ensures peer review protection are limited. In the absence of such pathways, practice evaluation occurs either 1) as a siloed function within each institution, introducing risk because of the hampered inability to compile and share information about adverse events and trended performance; or 2) with informal, unprotected sharing of information, introducing risk because of violation of peer review, as well as the lack of formality and rigor.

**Impact**

The establishment of a standardized system to assess network level performance in a peer-protected environment will improve tracking of patient safety risks, and mitigate a broad and substantial source of risk related to hospital network expansion. The toolkit design is scalable for broad adoption and therefore has the opportunity to broadly impact patient safety and mitigate risk within the BID network, the CRICO system, and beyond.

**Introduction**

Facilitated by the Patient Safety and Quality Improvement Act of 2005 (PSQIA), Patient Safety Organization (PSO) membership offers a unique opportunity to improve care delivery by fostering cross-collaboration in quality and safety between hospitals, provider groups, and other healthcare providers. Through the establishment of PSOs, the PSQIA encourages health care providers to share quality, root cause analysis and medical error information to improve the quality and safety of health care delivery without fear of legal discovery or tarnishing of professional reputations.

1 The Patient Safety and Quality Improvement Act of 2005 (42 USC 299b-21 et seq.)
There are currently 85 PSOs listed by AHRQ (https://www.pso.ahrq.gov/listed). The structure, function, purpose and communities served by these various PSOs vary, but are unified by an overarching mission of improving patient safety.

Implementation in 2010 of the Patient Safety Rule of the PSQIA established eight required patient safety activities of AHRQ listed PSOs:

1. Efforts to improve patient safety and the quality of health care delivery;
2. The collection and analysis of patient safety work product (PSWP);
3. The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
4. The utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
5. The maintenance of procedures to preserve confidentiality with respect to PSWP;
6. The provision of appropriate security measures with respect to PSWP;
7. The utilization of qualified staff; and
8. Activities related to the operation of a patient safety evaluation system (PSES) and to the provision of feedback to participants in a PSES.

What is Patient Safety Work Product? PSWP is confidential data with federal confidentiality provisions conferred by the PSQIA. PSWP may include data, reports, records, memoranda, analysis (such as Root Cause Analyses), or written or oral statements (or copies of any of this material), which could improve patient safety, health care quality, or health care outcomes AND that:

• are assembled or developed by a provider (solely) for reporting to a PSO and are reported to a PSO, which includes: (i) information that is documented as within a PSES for reporting to a PSO and (ii) such documentation or data that entered the PSES; OR
• are developed by a PSO for the conduct of patient safety activities; OR
• identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

Additionally, PSWP is privileged from administrative, disciplinary, civil, and criminal proceedings (not subject to subpoena) and is confidential; PSWP also may be Personal Health Information (PHI) under the Health Insurance Portability and Accountability Act (HIPAA) and subject to other privacy and security regulations. With the privilege of federally conferred confidentiality provisions comes a personal responsibility or ‘burden’ not to disclose the information (PSWP), including the potential for a personal fine of $11,940 imposed by the Office of Civil Rights. The information does not lose its protections even if it is accidently released; the next person who shares the information (re-disclosure) could also be subject to a fine.

1 The Patient Safety and Quality Improvement Act of 2005 (42 USC 299b-21 et seq.)
What is a Patient Safety Evaluation System? A PSES is designed and maintained for the collection, management, or analysis of information for reporting to or by a PSO. It describes what information is submitted to and fed back from the PSO that can be used to improve patient safety, health care quality, and health care outcomes (may be targeted initiatives). This may include:

- Event review, analysis and action plans
- Recommendations to continuously improve patient safety, healthcare quality, and health care outcomes
- Final decisions as to which data will/will not be reported to the PSO
- The actual process of submitting data into the PSO
- Any receipt and usage of feedback or recommendations from the PSO for patient safety activities

The rigor of developing and maintaining a PSES is beyond the scope of this toolkit. Resources are available online from organizations such as the Alliance for Quality Improvement and Patient Safety (AQUIPS) – [https://www.allianceforqualityimprovement.org/resources](https://www.allianceforqualityimprovement.org/resources).

A role for PSO membership in response to health system mergers and acquisitions: Member organizations of a PSO interact with a PSO through their own PSES. A member organization’s PSES is designed and maintained for the collection, management, or analysis of information for reporting to or by a PSO and may exist anywhere that patient safety activities occur in a health care entity. It encompasses any supporting documentation, information, or analyses done to determine which data is sent to the PSO.

Under certain provisions specified by the PSQIA, a PSO may enter into an ‘enterprise agreement’ with a health system. The enterprise agreement in turn permits the health system to create an ‘enterprise PSES’ that encompasses the individual PSEs of its ‘owned’ hospitals and provider groups, subject to criteria set forth by the PSQIA and AHRQ.

An enterprise PSES affords a unique opportunity for networked hospitals and provider groups to share internally certain patient safety activities and RCAs across their hospital licenses and medical staffs as designated PSWP. ‘Safe table convenings’ can be hosted by the health system within the construct of the linked PSEs of its affiliated entities, providing a protected forum for discussion and analysis of shared patient safety concerns. Information discussed in the safe table forum (PSWP) is governed by the PSQIA and is not discoverable, nor subject to subpoena. The environment is akin to the peer review environment that exists in some states; however, protections extend beyond a hospital’s traditional peer review structure. It may also include a broader definition of healthcare provider (as per the PSQIA - e.g. electronic health record vendor, retail pharmacy, private practice physician group, etc.) than is traditionally described in medical staff bylaws or recognized under state law. This ‘safe’ environment fosters rich, robust discussion and sharing of knowledge from which the health system may generate and promulgate best practice guidelines and risk mitigation strategies across its member hospitals, informed by the engagement of frontline providers and subject matter experts.

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Driven by market forces and consumer demand for improved access to healthcare, the integration of hospitals and provider groups into merged health systems continues to transform the delivery of healthcare. Coordination of care across care transitions, via disparate electronic health records, and spanning patient transfers between affiliated entities poses unique patient safety challenges. Peer review, if supported by state statute, may not extend across hospital licenses, limiting robust protected, peer review at a network level. An enterprise PSES thus provides opportunities to internally align best practices, improve patient outcomes and share certain peer review materials as PSWP, while conferring federal confidentiality protections to these patient safety activities.

A patient safety evaluation system (PSES) along with Patient Safety Organization (PSO) membership confers privilege and confidentiality protections\(^1\) that can assist hospitals in improving patient safety in this ever shifting healthcare environment. Root cause analysis, safe table convenings, and analysis and deliberations conducted within a PSES are tools PSO members can use to achieve these goals.

**Toolkit**

This toolkit is intended to assist hospital networks in creating a framework to evaluate quality, safety, and outcomes of programs and clinical practice that span separately-licensed hospitals for the purposes of improving patient safety. It is accompanied by the attached flowchart, which illustrates the steps to accomplish this using a PSES/PSO structure. This toolkit is not intended as legal advice for establishing such a mechanism. As such, it is recommended that legal counsel be engaged to inform the design a tailored program for a clinical practice evaluation.

For this evaluation, Beth Israel Deaconess Medical Center (BIDMC) developed a framework for the bariatric surgery service line at BIDMC and BID-Milton, another member hospital within the BID network. This framework is outlined below.

**Step 1: Identify PSO for Project**

BIDMC is a member of a PSO, specifically the Academic Medical Center Patient Safety Organization (AMC PSO). Therefore, for this evaluation, BIDMC did not need to identify or establish membership in a PSO.

**Step 2: Develop an enterprise PSES for Project**

A PSES is a system of collecting and analyzing data and developing feedback and clinical solutions at a provider facility and separately at the PSO. The policies and procedures developed for the PSES detail what information is designated as PSWP, how information becomes PSWP, who can access PSWP, how PSWP will be collected and analyzed, how PSO feedback will be communicated, documentation and archiving of PSWP, and the circumstances under which the PSWP collected could trigger investigation and analysis outside of the PSES, if warranted, which could lead to disciplinary actions.

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\(^1\) The Patient Safety and Quality Improvement Act of 2005 (42 USC 299b-21 et seq.)
For this project, a project-specific PSES was established within BIDMC’s existing enterprise PSES.

**Step 3: Identify sites, clinical area and providers for review**

BIDMC and BID-Milton were selected because both organizations have Level 1 ACS accredited bariatric surgery programs and at least one surgeon performs bariatric surgery at both sites. With respect to data and metrics collection, both sites comply with established monitoring tools and metric reporting to meet accreditation requirements and therefore have data necessary for the clinical evaluation of the two bariatric surgery programs. This is important to ensure that the scope of the pilot testing is manageable and greatly facilitated measure selection and access to established data sources.

**Step 4: Identify key team members for the project, and conduct training**

Team members should include key leadership, clinicians and staff and ensure sufficient resourcing of data collection and project management.

For this evaluation, the team included the Principal Investigator (the Chief Medical Officer at BID-Milton), surgical leadership, surgeons and program staff in the bariatric surgery programs at both sites, a Project Manager, a Data Analyst, and a legal consultant with expertise in patient safety organizations.

All team members who have access to patient safety work product must be trained regarding the confidentiality and security of PWSP. Model confidentiality training slides and acknowledgement are included as an attachment.

**Step 5: Identify key measures for comparing outcomes**

Identify a set of measures that are standardized across the study sites and that are tailored to compare surgical outcomes. When comparable, organizations may rely on clinical data, physician benchmarking reports, performance improvement indicators, or other peer review data sets.

This step can also be time-consuming. A helpful tactic when selecting measures is to identify accreditation organizations or mandated reporting standards that exist in the specified clinical area, building on those established measures, as appropriate.

For this evaluation, a subset of the measures required by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) was selected. While provider benchmark reports included some relevant measures, these reports were specific to bariatric surgery. While not an insurmountable challenge, using these reports would have added complexity related to data cleaning. In addition, the MBSAQIP reports were updated more frequently and therefore provided more current data.

**Step 6: Obtain data from sites for outcome comparison and analysis within the Enterprise PSES (PSWP)**

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There may be organizational approvals required before obtaining access to data for these purposes. Using our focus on bariatric surgery as an example, such approvals were expedited, as this evaluation requested information from the surgical departments at BIDMC and BID-Milton that was also reported to an accreditation organization. Information provided to an accrediting body is treated as confidential information and may be PSWP under certain conditions. The information collected in the PSES may be PSWP if this information is disclosed to the accrediting body under a permissible disclosure. If not, the information collected may be PSWP if the information is extracted from the original forms to conduct further analysis. The extracted information must be reported to a PSO to retain the PSWP protections. The analysis and deliberations conducted inside the PSES or PSO using the information extracted from the forms is PSWP.

**Step 7: Submit measures as PSWP to PSO for additional analysis**
The data and initial analysis is reported as PSWP to the PSO for analysis. File transfer protocol permission may be required to report this information to a PSO.

**Step 8: Receive de-identified analysis from PSO into the Enterprise PSES and evaluate key findings**
In this step of the process, the project receives de-identified analysis from the PSO containing key findings developed from the analysis – for example, the identification of potential risks.

**Step 9: Initiate additional patient safety investigation/RCA/QI activity within the Enterprise PSES based on PSO analysis, as appropriate**
Additional analysis is undertaken by the hospital system within its enterprise PSES based on PSO analysis. Submission of RCA PSWP can provide a rich database of patient safety events that is curated by the PSO and analyzed within the PSO’s PSES for emerging patient safety trends.

Based on statistically significant different site differences in one outcome category under our project (pre-operative weight loss), the bariatric surgery programs at our two sites met in a PSES safe table convening forum to share best practices and develop standardized approaches to pre-operative counseling and dietary recommendations to trial at both sites.

**Step 10: Conduct PSES ‘Safe Table’ to share lessons learned with key quality and safety leaders at participating institutions**
Safe tables facilitate transparent conversation, foster trust and promote the development of cross-institutional relationships; this contributes to the creation of a learning collaborative from which best practice guidelines and risk mitigation frameworks can be generated. A safe table confidentiality agreement is included as an attachment.

For this evaluation, findings were presented to key quality and safety leaders at our two sites. In addition, a separate safe table presentation was conducted within the PSES for leaders of the integrated bariatric surgery program across both sites. This approach enabled us to tailor presentations for each audience. For example, the discussion with the quality and safety

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leaders focused on more global quality and safety factors, while the discussion with the bariatric leaders probed deeper into the bariatric-specific data for a more detailed discussion of the differences in clinical outcomes and of the clinical pathways that had developed organically at each site.

**Step 11: Integrate refined list of measures into local safety peer review scorecards for use in QI and privileging OPPE monitoring (non-PSWP), as appropriate**

An example of what organizations can develop in this area is a scorecard detailing key process and outcome measures. In this evaluation, a scorecard was developed that tracks measures including pre-operative weight loss, as noted above. Another measure that showed statistical significance between the two sites - length of stay – was also included on the scorecard.

**Step 12: Initiate separate local peer review outside of the PSES of any signals of individual provider performance issues (FPPE) and/or system tool and resource opportunities for improvement, as appropriate**

The process outlined by this toolkit may identify areas of risk that warrant further investigation. While PSWP should not be used for disciplinary actions, if a review of PSWP data uncovers signals of risk relative to provider performance, it can trigger a separate, de novo investigation, analysis and peer review process outside of the PSES. Because we did not identify any variance in the data that identified such risk, we did not pursue this route within our project.

**Step 13: Securely archive PSWP**

All PSWP should be kept secure, stored within secure servers behind a firewall and password protected. PSWP should only be accessible to those identified in the PSES, but can be voluntarily disclosed through a disclosure permission and results of this study can be used to improve the quality of bariatric care nationwide. The process of disclosure permission is described within the PSQIA\(^1\) and related implementation patient safety rule of 2010 and is beyond the scope of this project.

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1. Identify PSO for project

2. Develop Enterprise PSES for project

3. Identify sites, clinical area and providers for review

4. Identify key team members for project, and conduct confidentiality trainings

5. Identify key measures for comparing outcomes

6. Obtain data from sites for outcome comparison and analysis within Enterprise PSES (PSWP)

7. Submit measures as PSWP to PSO for additional analysis (Analysis Pathway)

8. Receive de-identified analysis from PSO into Enterprise PSES and evaluate key findings

9. Initiate additional patient safety investigation/RCA/QI activity within Enterprise PSES based on PSO analysis, as appropriate

10. Conduct PSES ‘Safe Table’ to share lessons learned with key quality & safety leaders at participating institutions

11. Integrate refined list of measures into local safety/PI/peer review scorecards for use in QI and credentialing OPPE monitoring (non-PSWP), as appropriate

12. Initiate separate local peer review of any provider performance issues (FPPE) and/or system tools & resources OFI outside of PSES, as appropriate

13. Securely archive PSWP