PATIENT SAFETY MANUAL:
"GUIDELINE FOR PATIENT SAFETY PROGRAMS IN ALL HEALTHCARE SETTINGS"
APPROVED BY HCQCC COUNCIL - MAY 16, 2012

INTRODUCTION

"We envision a system of care in which those who give care can boast about their work and those who receive care can feel total trust and confidence in the care they are receiving."

Donald Berwick, MD, MPP

Providing high quality, safe, and effective patient care is a central goal of all clinicians. Stemming from the early recognition by Hippocrates of the potential for harm to patients through the delivery of care millennia ago, and advancing through the broad acceptance of the tenets of "first do no harm," patient safety initiatives have moved to the forefront of health systems redesign in the last decade. It was not until 1999, with the release of the seminal Institute of Medicine report, "To Err is Human," that the regularity and magnitude of avoidable adverse events was broadly recognized. The innovation of patient safety programs across health care settings has enhanced the recognition, understanding, reporting, and prevention of medical errors. Informed by simple practices common in fields such as business and industry, patient safety programs may consist of education, adverse event reporting, technological advances, or financial incentives and disincentives to drive improvement of care.

The Massachusetts Health Care Quality and Cost Council (HCQCC) has been charged by the Massachusetts legislature with improving patient safety in all health care settings across the Commonwealth. Methods to ensure safety may be basic or complex; they may involve sizeable financial investments or modest shifts in practice culture driven by leadership committed to ensuring patient safety. In this guide, we seek to provide a generic, simple framework that approaches patient safety program development in a way that applies in all settings of care.

We recognize that each organization is unique, and organizations may be at different points along their journey to achieve patient safety. This manual provides some general ideas around foundations of patient safety, basic elements of a patient safety program, and suggestions to get started or to maintain your program, to review as your organization reflects on its individual patient safety plan. We have worked closely with professional associations and state agencies to develop this manual. As you begin to consider and then implement a patient safety program, your association can serve as a resource, providing opportunities for finding, and sharing, best practices.

Karen Boudreau, MD
Chair (2012), Quality and Safety Committee,
Massachusetts Health Care Quality and Cost Council

FOUNDATIONS OF PATIENT SAFETY

"Every system is designed to get the results it gets…"

Paul Batalden, MD

At the basis of patient safety are both *systems* and *culture*.

Systems

Your office or practice setting is a complex system, and there are multiple processes within this system that help you accomplish your everyday work. It is these work processes that produce the outcomes that patients experience. When something goes wrong, we know it is likely a bad process--not a bad person--that is at the root of the problem. To improve flawed systems, and subsequently outcomes, it is helpful to examine and improve the work *processes* to make them as safe and reliable as possible.

Culture

A safe practice is best supported by a culture that values:

Safety as a prerequisite - that the organization considers safety a necessity.

Clear and open communication among staff - supported by a sense of security and a belief that no one will be punished or humiliated, but encouraged and supported, for speaking up with ideas, questions, concerns or mistakes[1].

A constructive learning system - where information and data is used for learning and not for judgment.

Teamwork - in which every staff member has skills and ideas to contribute to improvement work.

Input from patients and families - feedback from patients and families is important to ensure the improvement process is moving in the direction to help the very people the organization aims to serve.

JUST CULTURE: Building a "just" culture is the result of: (1) leadership that prioritizes and models values that focus on root cause identification and problem solving, not blame; (2) processes and policies that reflect and support the values; (3) staff and members that make these values a part of their everyday work.

"People make errors, which lead to accidents. Accidents lead to deaths. The standard solution is to blame the people involved. If we find out who made the errors and punish them, we solve the problem, right? Wrong. The problem is seldom the fault of an individual; it is the fault of the system. Change the people without changing the system and the problems will continue."

ELEMENTS OF A SAFE PRACTICE

Here are a few basics principles and structures to consider in your practice setting as you are building your patient safety program:

1. ***Leadership for Safety*—** The "Leadership" is the head of the practice or the organization, the person/people who are in charge of making major decisions for the system of care. It might be an individual clinician who owns the practice, a C-suite executive, or a senior staff member. Leaders are ultimately responsible and accountable for safety. He or she ensures that safety is considered a necessity and is instrumental in building safety into the culture of the practice. Leaders can demonstrate their commitment to safety both by the resources (including time and attention) they devote to safety efforts as well as modeling the behaviors necessary for a safe culture.

    A. **Responsibility and accountability—**The leadership should actively support a safety culture. In addition, should there be a safety issue, the leadership should take responsibility and ensure that a full analysis of the issue, identification of potential problems, and a plan for addressing the problems all occur. The leadership should ensure that clear communication about the safety issue occurs with the patients/families involved and with the staff. (See "When something goes wrong" below)

    B. **Building a safety culture**--Leadership also supports the safety culture by participating in and modeling the values of a safe culture described above. A few successful examples of how to enhance the safety culture are:
        i. Walk rounds (i.e., regularly scheduled visits to the frontlines to experience current practices, hear feedback from frontline staff),
        ii. Supporting and encouraging safety projects (examples: offering leadership advice on culture; voicing open public support for organizations safety efforts; resource support for projects if necessary/possible)
        iii. Modeling the attributes of safe culture in all interactions: collaboration, clear and open communication, asking questions to learn, encouraging suggestions from all staff regardless of their role in the practice;
        iv. Ensuring that safety is on the agenda for staff meetings and is approached in a constructive way
        v. Ensuring that discussions about safety happen at board level, if the organization has a governing board.

    C. Encouraging development of reliable processes
        i. Supports and encourages staff to build processes for standard care and communication
        ii. Supports continuous process improvement in all areas (see below).

2. *A Point Person for Safety* **(patient safety officer, safety champion, safety coordinator) --**Identify a staff member who can serve as the day-to day champion of safety. This does not have to be a full-time job. In fact, some of this point person's day-to-day responsibilities may already be the responsibilities of a current staff member, or may be easy to incorporate into a current staff member's duties **(**could be a practice manager, a head nurse, a care provider, or any other staff member who has a special interest in safety)**.** Supported by the leadership, this point person could be responsible for:

   A. Ensuring that safety discussion is on the agenda for staff meetings;
   B. Ensuring that there is follow-up on any preventive/proactive process improvement initiatives;
   C. Ensuring that there is follow-through evaluation of adverse event reports (see below);
   D. Serving as the contact if a patient asks to speak to staff about a safety issue;
   E. Serving as the liaison between frontlines and leadership, and between patients and leadership;

3. ***Process Improvement***: Examine your current processes. Think about what could go wrong and prevent it before it happens. To start (or also on a maintenance level), meet with staff in the office and discuss "What keeps you awake at night? How are you worried a patient might be hurt/have a bad result in our setting?" Sometimes the number of suggestions for changes can seem daunting. However, you can start small and "improve your way" into a more reliable process: (Insert reference for Model for Improvement here)

   A. Identify from staff suggestions potential "bad results."
   B. Analyze current processes--what happens in your processes that might produce that result?
   C. Consider what changes in processes might prevent this from happening
   D. Analyze the change possibilities and **identify the changes** you think are most likely to help.
      - Don't be daunted by these changes—consider starting small so that you can start acting right away!
      - Ask—what change can you try next Tuesday?
      - To keep the scope manageable, you can consider trying the change in one small area first (one change with one patient, with one staff member).
   E. Think if you can **identify an outcome measure** of that change.
   F. **Make those changes** in your processes
   G. **Measure those processes** over time and see if you think they have made an improvement. Consider posting the data in an area where staff can see their progress and get feedback on the changes.
   H. **Learn from the data—**
      - Was there an improvement—can you replicate and/or spread the change?
      - Was there no improvement—re-examine—why not? Perhaps consider a different change?

I. Here are some trigger questions to generate examples of process areas to consider:
   - Transitions—patients moving into or out of your facility to another;
   - Communication—passing information to patients; receiving/giving information to other institutions;
   - Care processes specific to your industry;
   - Needs of special populations for whom you care? (elderly, disabled, children? For example, falls...);
   - Medication management—ordering, administration, reconciliation, transfer of information;
   - Equipment specific to your industry or practice: safety issues in use or maintenance.

"The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes."

Lucian Leape, MD

4. ***When something goes wrong***: Identify a process to handle a situation if something goes wrong. You can also seek guidance from your professional organization to see if they already have a format for such processes.
   A. Consider your current reporting process:
      - How does someone (patient or staff) report a problem; and
      - Who collects the information?
      - How is it collected/recorded?
      - What information is collected/recorded?
   B. What happens to the report once completed by the patient/staff:
      i. Internal communication about the report to leadership,
      ii. Consider initial response:
         a. With the patient and family
            - Timely communication from leadership and continuing contact throughout process
            - Consideration of providing not just information but support and care
            - Invitation to participate in analysis of what caused the problem
         b. With the staff
            - Clear communication as to what occurred
            - Clear communication as to what is the ongoing discovery process
            - Clear communication as to ongoing support for family
            - Consider resources for staff if they are stressed and an invitation to participation in analysis of what caused the problem, as appropriate
         c. With regards to the event
            - Make sure that there is a thorough analysis of the event, including a full account of what happened from all involved (patient, family, and staff)

- Examine what were all the contributing factors (ask "why" five times)

C. Process improvement (as detailed above):
   i. Consider what changes in processes might have prevented this from happening
   ii. Identify the change(s) you think could help
   iii. Identify a way to measure the change
   iv. Make those changes in your processes
   v. Measure those outcomes over time and see if you think they have made an improvement
   vi. Learn from the data—improvement/no improvement? Spread change or make a new change?

5. **Learn from patients and families—**Asking patients and families directly for feedback or including them in planning can provide valuable input and insights and constructive suggestions for your practice. They often appreciate the invitation to provide feedback. By hearing about concerns, issues, or suggestions ahead of time, you have the opportunity to address them before they become bigger problems
   A. Discuss how your office would provide the opportunity for patients and families to express concerns. Consider a standard process for patients to report concerns, problems and adverse events. This process should include:
      1) a way for patients to speak to a safety contact person to express concerns,
      2) a way to document the concern, and
      3) a way to roll the report into a process for further inquiry/exploration.
   B. Develop a process for communications so that patients and families know you would like to hear from them. Some examples might be suggestion boxes or regular patient satisfaction surveys (**resources here?**). Consider incorporating review of these suggestions with leadership and/or at staff meetings.
   C. Consider including patient representatives on planning activities or safety initiatives.

GETTING STARTED

Don't forget—you can start small and see how it goes! Some suggestions for how you can get started:

- Ask leadership to read this general guide, to help ensure a common understanding of the basic elements of the patient safety program.
- Identify a few staff (ideally at least two) in your office who would like to help start the work
- Ask these staff members to read this guide, discuss it together—what major questions arise? What are questions specific to your industry or your practice that need to be clarified with regards to the foundation elements?
- Leadership should identify who will serve as the day-to-day patient safety point person.

- The safety point person can start to develop a plan of how to develop the basic elements of a patient safety program. Ask the staff to help in collecting the information you need to start.

Possible resources include:

- Discussions and feedback during staff meetings;
- Your professional association – see if they have help to offer in starting a patient safety program, answering the industry specific questions, or linking you with another organization in your industry who has already made some inroads into patient safety;
- Your malpractice insurer, to see if they have help in " risk management" or "loss prevention" strategies;
- Researching the literature or other outside agencies resources;
- Input from patients—suggestion boxes, patient satisfaction surveys, patient interviews.

"Safety is a core value, not a commodity that can be counted, which shows itself only by the events that do not happen."
Erik Hollnage

MAINTAINING A PATIENT SAFETY PROGRAM

How to ingrain patient safety in your culture

- Keep it on the agenda—sometimes you don't have much time, but keep the discussion going. Keeping safety as a regular item on the agenda will be one way of showing commitment to the effort, and will set aside time to talk about current status.

- Keep checking with your professional association, read their newsletter, watch for committees or educational programs that might help

- Remember that improvement can start small—trying to change too much at one time can be overwhelming. If you make small changes, evaluate them, and continue to learn from the data, you can "improve your way" into a new process, in which the small changes become bigger changes;

- Get everyone engaged—rally around the shared sense of purpose of safe care for your patients. Involvement of individuals can be on the feedback and idea level, or could be at varying levels of action.

- Display your progress (in data) and celebrate your successes—nothing is more gratifying than knowing that the changes you are making are making a difference for patients and staff!