Lawrence Patient Safety Award 2007

Implementation of a High-Alert Medication Program

Abstract

Introduction: Greater than 500,000 doses of high-alert medications are administered throughout the Kaiser Permanente Northern California (KPNC) Program on an annual basis. High-alert medications (HAM) carry a higher risk of harm than other medications and errors in the administration of HAM can have catastrophic clinical outcomes. The purpose of this project is to ensure safe medication practices and to eliminate medication errors that cause harm to our patients.

The Program: KPNC leadership, physicians, nurses, pharmacists, quality leaders, and labor unions worked with regional and local medication safety committees to: 1) standardize high-alert medication-handling practices; 2) enhance education programs related to medication practices, embedding these into annual core competencies of all staff who handle high-alert medications; 3) develop monitoring functions at both the regional and local levels to ensure sustainability and ongoing systems improvements. Begun in December 2005, this program covers the delivery of high-alert medications across the continuum of care and affects all patients receiving HAM.

Measures: The initial phase of the monitoring process was put in place to measure compliance with implementation. Over the first few months of the program the 90% minimal threshold was surpassed with regional overall compliance of 95%. Following this initial process, the Regional Medication Safety Committee developed monitoring tools. Department managers carry out these concurrent observational audits at the medical centers with oversight by the Assistant Administrators for Quality and Service. These audits are designed to measure whether or not all medications on the HAM list are handled specifically to policy requirements, eg, independent double-checks, HAM stickers, etc. Audit specifications are provided for each audit tool. Medical Center audit results from the third quarter of 2006 through the third quarter of 2007 have shown a regional aggregate of 97.7% compliance. As the high percentages of compliance have held constant over time, more actionable metrics are being put in place for 2008.

To determine whether or not the program is reducing HAM errors, data from the regional Quality and Risk database (MIDAS) related to all high-alert medication errors was reviewed. Two interventions were of note: in July of 2005, there was a renewed effort to educate leaders, managers, physicians, and staff on responsible reporting in a “just culture” and the introduction of the new Responsible Reporting Form. An increase in reporting was noted at this time. In December 2005, the HAM program was introduced. There is a statistically significant drop in errors reported for 23 consecutive months following this program. These findings were similar for all phases of the delivery process. A powerful indicator of improvement is the average days between major injury and death. As of November 30, 2007, it has been 232 days since the last significant negative event was reported due to a HAM.

Conclusion: This program has been implemented in all of the KPNC Medical Centers and is in the process of being implemented in all KP regions. This spread has been endorsed by the Medical Directors Quality Committee and by the KP Boards of Directors. The Interregional Medication Safety Committee is overseeing the spread process. A toolkit containing all of the required tools plus additional materials and information has been developed and made available throughout KP. The program is the recipient of the 2007 Lawrence Patient Safety Award.
Introduction

According to the Institute of Medicine’s report in 2006, Preventing Medication Errors, an estimated 380,000-450,000 preventable adverse drug events (ADEs) occur in hospitals each year. These errors most frequently occur in the prescribing and administering stages. Medication errors are a significant and often preventable health care problem. Although many medication errors may not cause grave harm to patients, some medications are known to carry a higher risk of harm than other medications and errors in the administration of these medications can have catastrophic clinical outcomes. These medications are identified as high-alert medications (HAM) and require special considerations. One of the National Quality Forum’s 30 Safe Practices for Better Healthcare is to “identify all high-alert drugs, and establish policies and processes to minimize the risks associated with the use of these drugs.”

Greater than 500,000 doses of HAM are administered throughout Kaiser Permanente Northern California (KPNC) on an annual basis. Following three major adverse medication safety events, it was determined by KPNC leadership that there must be a more focused approach for HAM. To ensure safe medication practices and to eliminate medication errors that cause harm to our patients, KPNC implemented the High-Alert Medication Program (HAMP) in December of 2005.

Table 1. High-Risk Medication Safety Task Force

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<th>Name</th>
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<tr>
<td>Current</td>
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<tr>
<td>David Campen, MD</td>
<td>Northern California Regional Offices; Santa Clara Medical Center</td>
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<tr>
<td>Molly Plau Clopp, RN</td>
<td>Northern California Regional Offices</td>
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<td>Suzanne Graham, RN, PhD</td>
<td>Northern California Regional Offices; Southern California Regional Offices</td>
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<td>Nicholas E Kostek, RPh</td>
<td>Northern California Regional Offices</td>
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<td>Rich Levy, PharmD</td>
<td>Southern California Regional Offices</td>
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<td>Julie Nunes, RN</td>
<td>Northern California Regional Offices</td>
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<td>Maryjo Williams, RN</td>
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<td>Emma Baron, RN</td>
<td>formerly Northern California Regional Offices</td>
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<td>Lynda Bayless, RN</td>
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<td>Kathy Brown, RN</td>
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<td>Eric Enders</td>
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<td>Suzanne Graham, RN, PhD</td>
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<td>Karen Grisnak, RN</td>
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<td>Terry Heywood, MD</td>
<td>Walnut Creek Medical Center</td>
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<td>Pat Irving, RN</td>
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<td>Jackie Killeen, RN</td>
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<td>Mary Kirkwood, RN</td>
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<td>Nicholas E Kostek, RPh, MS</td>
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<td>Mary McFadden, RN</td>
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<td>Janet Nagamine, MD</td>
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<td>Julie Nunes, RN</td>
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<td>Doug O’Brien, PharmD</td>
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<td>Lynn Paulsen, PharmD</td>
<td>Cross Regional Patient Care Services</td>
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<td>Kimberly Powell, RN</td>
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<td>Julie Read, RN</td>
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<td>Vincent Reed, RN</td>
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<td>Anita Zuniga, RN</td>
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Implementation of a High-Alert Medication Program

Background

In July of 2005, a 21-year-old patient was admitted to the hospital for lymphoma. This patient began receiving chemotherapy and was responding well to the treatments. On August 26, 2005, the patient received what was to be the fourth chemotherapy treatment, injected intrathecally. Three days later, this 21-year-old died from a lethal medication error. What had been injected in the patient’s spine on August 26 was not the prescribed treatment but rather vincristine, a chemotherapy medication intended for another patient, that is lethal when administered intrathecally.

Multiple system failures and human errors led to this tragic incident. Although the pharmacist noted that there were four chemotherapy medication orders for two patients that day, the medications were mixed up and delivered to the incorrect nursing units. When delivering the medication, the pharmacist placed the syringe directly in the refrigerator rather than performing face-to-face delivery to explain safety precautions necessary with this drug. Additionally, the vincristine was not labeled and packaged according to the manufacturers’ recommendation and did not display the warning, “Fatal if given intrathecally. FOR IV USE ONLY.” Neither the nurse nor the physician checked the label on the syringe with the patient’s name or used the “five rights” (5Rs) right drug, right dose, right time, right route, right patient—of medication administration before administering the medication. The nurse removed the medication label before handing the syringe to the physician so as to see the graduations clearly. Thus, the physician had an unlabeled syringe. This series of errors was preventable if better systems had been in place to prevent this tragic occurrence.
Objectives
The outcome of this event was the creation of the HAMP in the Northern California Region. The overall purpose of the HAMP was to ensure safe medication practices and to eliminate medication errors that cause harm to our patients. These goals were to be achieved by:

- Identifying high-risk and problem-prone medications as HAM
- Standardizing HAM handling practices
- Enhancing education programs related to HAM practices, embedding these into annual core competencies of all staff who handle medications
- Developing monitoring functions at both the regional and local levels to ensure sustainability and ongoing systems improvements.

Approach
In November of 2005, under the direction of Northern California leadership, the Regional Medication Safety Committee (RMSC) chartered the High-Risk Medication Safety Task Force (Table 1) for the purpose of drafting a proposal for standardizing the handling of HAM throughout KPNC. This core multidisciplinary group included Kaiser Foundation Hospital, the Permanente Medical Group and the California Nurses Association (CNA). Membership was brought together for a full-day, intensive decision-making event to establish a plan, determine the working groups, define the scope, and establish the limited list of HAM, processes, and patient types that would form the program for KPNC.

Using the current literature, recent medication-related events in KPNC, and the expertise of the participants, the High-Risk Medication Safety Task Force broke down into working groups to develop the HAM list. Each group had content and experience experts and was charged to bring forth the listing of drugs, methods of administration and patient-specific requirements that the large group would evaluate. Decision making was by consensus and the HAM list and management requirements were established. (See sidebar for list of HAM.)

The Task Force then determined that the HAMP would have the following requirements:

- The HAM list, drug concentrations, and management requirements would be standardized at all facilities throughout the region
- Any change to the list would require approval by the RMSC
- The HAMP would apply across the continuum of care, including specialty areas
- Senior leadership would ensure the appropriate resources were available for design, implementation, and equipment requirements.

A team of pharmacists, nurses, and quality practitioners, with the guidance of physician partners, developed the policies and procedures of the HAMP (Table 2). During a period of two months, these were sent to subgroups of staff for comment and through a dynamic change process the policies and procedures were finalized into a working document. These received final approval from leadership and the RMSC.

A communication plan was developed to ensure that the message of medication safety would be consistent and that everyone in KPNC would be aware of the program. Support for the program at the facility level was critical and specific communication steps were taken to enlist the support of local leadership to ensure success.

An education plan was established to accomplish the goal of training all pharmacy, nursing, and medical staff within a very short time frame. Standardized education tools were developed for use across the region. Training was accomplished in less than two months.

An audit subgroup of the RMSC was established to design monitoring tools and procedures to ensure complete implementation, staff competency training and the consistent application of the requirements of the program. Regionally, reporting was to be ongoing, using the regional quality and risk database (MIDAS; MIDS, Inc; Tuscon, AZ) to track the trends in HAM involved in adverse events.

Kaiser Permanente Northern California High-Alert Medication List (November 2007)
1. Continuous IV heparin infusions
2. Continuous IV insulin infusions
3. Neuromuscular blocking agents
4. IV cytotoxic chemotherapy infusions
5. Sodium chloride infusion >0.9%
6. Potassium injection (chloride, acetate, and phosphate) >0.4 mEq/mL
7. Magnesium sulfate infusions >100 mL
8. Alteplase (t-PA, Activase) infusions
9. Tenecteplase (TNKase) injections
10. Vinca alkaloids (VinCRIStine, VinBLAStine, Vinorelbine)
11. Narcotic/opioid infusions, including PCA
12. Epinephrine, norepinephrine, isoproterenol infusions
13. All medications administered via intrathecal route
14. All medications administered via epidural route
15. NICU: All doses of IV and oral medications (except for oral vitamins or iron)
16. Pediatrics (Ages 0-13): All medications on the ADULT HAM list; all doses of IV medications given in critical care areas, including Emergency Department; all medications used for procedural sedation (except when administered by anesthesia provider); digoxin (all routes); and chloral hydrate (all routes)
### Table 2. Kaiser Permanente Northern California High-Alert Medication (HAM) Policy abstract

<table>
<thead>
<tr>
<th>High-alert policies</th>
<th>Management requirements</th>
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| All HAM and routes  | • Independent double-check in the pharmacy for all pharmacy-prepared IV infusions of HAM and documentation on IV compounding profile/log book  
• Require independent double check at the bedside by two appropriate persons and documentation on medical record at initiation of administration, at bag change, at dose change, and at transfers/handoffs  
• Includes inpatient and outpatient settings  
• All physicians, nurses, and others who administer HAM will have medication administration training and will comply with regional policy  
• HAM will have red “high-alert” stickers  
• Anesthesia providers comply with the HAM list Policy and Procedure for Anesthesia  
• “Clinical Data Category” warning in Pyxis (eg, Caution: High-Alert Drug)  
• Use of “smart” pumps with patient safety software required when available  
• Emergency situations (eg, Code Blue) are excluded |

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<tr>
<th>Critically ill neonates</th>
<th>• All IV and all oral medications except oral vitamins and oral iron</th>
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| Pediatrics (0-13yr)    | • All medications on adult HAM list  
• All doses of IV medications in critical care areas, including Emergency Department  
• All medications used for procedural sedation except anesthesia provider  
• Digoxin (all routes)  
• Chloral hydrate (all routes) |

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<tr>
<th>All intrathecal medications</th>
<th>• Requires a “time out” in pharmacy and at medication administration</th>
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| All epidural medications    | • Use standard concentrations for infusions  
• Use color-coded or labeled tubing without injection ports, where feasible  
• Special labeling for containers |

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<thead>
<tr>
<th>High-alert medications</th>
<th>Management requirements</th>
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| Heparin infusion       | • Do not use unapproved abbreviations, ie, “µ,” in orders  
• Store vials separately from insulin  
• Standard concentration of 100 units/mL  
• Independent double-check at rate change required |
| Insulin infusions       | • Do not use unapproved abbreviations, ie, “µ,” in orders  
• Infusions compounded and dispensed by pharmacy  
• Standard concentration 1 unit/mL |
| Neuromuscular blocking agents | • Restrict floor stock to Emergency Department, Operating Room, Postanesthesia Care Unit, Critical Care and Cath Lab  
• Store separately with special labeling to differentiate from other meds  
• Use identification techniques (eg, labels, etc); shrink wrap not required  
• Confirm intubation status prior to administration |
| Cytotoxic chemotherapy infusions | • Independent double-check in pharmacy process  
• Use special packaging and labeling  
• Verbal orders not accepted  
• No dosing by course of treatment  
• Minimum set of information in medication orders  
• Verification of scheduled date and time of dose prior to administration  
| Vincristine, vinblastine and vinorelbine | • Dispensed in mini bag, rare exception for pediatrics, noncentral line  
• Requires a “time out” and independent double-check immediately prior to administration |
| Concentrated electrolytes | • Sodium chloride >0.9% infusion  
• Potassium infusions (chloride, acetate, phosphate) greater than 0.4 meq/mL  
• Restrict storage to pharmacy  
• Use premixed products when available |
| Magnesium sulfate infusion | • Bag volumes greater than 100 mL are high alert  
• Use premixed products when available  
• Standard concentration 40 mg/mL |
| Alteplase (t-PA, Activase) infusion | • Infusions compounded in pharmacy, emergency exceptions will be tracked  
• “Clinical Data Category” in Pyxis to differentiate product from tenecteplase (TNKase)  
• Special labeling requirements |
| Tenecteplase (TNKase) injection | • Independent double-check prior to administration  
• “Clinical Data Category” in Pyxis to differentiate product from alteplase (t-PA) |
| Narcotic/opiate infusions including patient-controlled analgesia | • Use standard concentrations for morphine, meperidine, and hydromorphone  
• Programming of pumps in process  
• Labeling to show “high-concentration” product to differentiate from standard concentration  
• Independent double-check at rate changes required |
| Epinephrine, norepinephrine, isoproterenol infusions | • Standard infusion concentrations for all continuous infusions  
• Independent double-check at rate changes not required |
HAMP relies on consistent practices throughout KPNC, use of state-of-the-art technology such as smart pumps for medication infusions, and thoughtful design and implementation of sound safety practices such as independent double-checking and hand-off communication skills such as the Nurse Knowledge Exchange.

**Data Collection and Analysis Process**

The first phase of the facility monitoring process was checking for compliance with implementation of the program. The implementation threshold was set at 90%. Four out of 18 facilities reported below threshold results. Corrective action plans were implemented and three of the four facilities subsequently reported results of greater than 98% compliance, bringing the regional overall compliance result to 95%.

Following this initial process, observational audit monitoring tools were developed (Figure 1). Department managers carry out these observational audits at the medical centers with oversight by the Assistant Administrators for Quality and Service (AAQS). These audits are designed to measure whether or not all medications on the HAM list are handled specifically to policy requirements. Audit results (regional averages) for the third quarter of 2006 were 97.3%; for the fourth quarter were 98%; for the first quarter of 2007 were 98.2%; and for the second quarter 97.2%; and for the third quarter 97.8%. The audit subgroup surveyed facilities regarding their experience of the audit process. Most respondents felt that the audits had been effective in monitoring the initial implementation of the HAMP policy, but that it was time to explore more actionable metrics that would support continued performance improvement.

The Institute for Healthcare Improvement (IHI) developed a trigger tool for measuring ADEs, as well as a set of global trigger tools to provide an easy-to-use method to accurately identify adverse events and to measure the rate of adverse events over time. Tracking adverse events over time is an important tool in determining if changes made result in improvements. The High-Risk Medication Safety Task Force worked with IHI to modify the trigger tool and, through small tests of change, piloted its use. In the first quarter of 2007, two facilities volunteered to pilot the use of the trigger tool methodology to focus on the care experience of patients receiving certain HAMs. The San Rafael Medical Center reviewed care of patients receiving opiates via patient-controlled analgesia (PCA) pumps and the San Francisco Medical Center reviewed care of patients receiving intravenous heparin. The trigger tools were designed to collect demographic, clinical process, compliance with policy, and outcome (harm) data. Twenty charts of patients from the respective populations were reviewed each month with review time intentionally limited to no more than 20 minutes per chart. Auditors worked together representing the following disciplines: pharmacy, quality, risk/patient safety and nursing. The results of the focused trigger tool pilot project on IV-heparin therapy at the San Francisco Medical Center revealed several opportunities for improvement that may not have been identified by other methods. On the basis of these findings the Medical Center was able to take steps to further improve processes in the delivery system for IV-heparin.

The Quality Liaisons (QLs) (CNA staff nurses mutually appointed by the CNA and KPNC) played a large role in determining areas of concern and creating solutions. When data showed that nurses were still not doing the 5Rs, a workshop was held with the QLs to determine the reasons. Through a Delphi process—a process of reducing ideas from brainstorming to key elements—the three major reasons were identified: interruptions, distractions, and rushing. The QLs then helped design small tests of change to rectify these areas. For example, the South San Francisco Medical...
Center piloted the use of yellow medication vests as a sign that a nurse was not to be interrupted because s/he was in the process of administering medications. A reduction in medication errors was noted as a result of this program. This vest program was presented at the California Nursing Outcomes Coalition Conference in Anaheim, CA, November 8, 2006, and discussed in the *Advance for Nurses* May 2007 publication. An article on the successes of these initiatives appeared in the Fall 2006 STEPS. Regional data was collected through the Responsible Reporting Form (RRF). KPNC employees use the RRF to identify any medication events—near-misses and ADEs. This data, with supplemental information when necessary, was imported into MIDAS. In January of 2006, the data collection process for HAM events was standardized in MIDAS to allow for tracking and trending of HAM events. The categories of data for medication events include: demographics of patient, time, unit, diagnosis, type of medication event, name of medication, HAMP type, outcome, including near miss (those events that do not reach patients), and other parameters associated with the event, including human factors.

**Implementation Considerations**

**Leadership Endorsement**

Key physician and nursing leaders from both the hospital and the Medical Group endorsed the program and created visible support through the use of e-mail communications and direct communication with Medical Center leadership. They worked with the established Regional HAMP Committee, the RMSC, and a small workgroup, nicknamed the HAMPsters, to create the policy and procedures and to establish the implementation plan. Weekly phone calls with the HAMPster group and the medical centers were implemented to ensure sustainability, lending their support to address barriers, and offering in-person presentations to the facility leadership team as needed.

**Communication and Education**

Routine phone calls were held with the medical center leaders accountable to implement the HAMP policy and procedure, to answer questions, to clarify misunderstandings, and to continue to communicate the consistent message. For the first few months of the program these calls were weekly. The calls are now monthly. The Task Force met with department chiefs, nursing leadership groups, and staff nurse leadership groups to convey the need for a consistent program approach. In addition, all nursing staff and others who give medications, such as radiology technologists, completed a self-study module and brief test on the 5Rs (five rights) of medication administration.

**Feedback Loop**

A process was established to allow medical centers to request changes to the policy. Those change requests...
Implementation of a High-Alert Medication Program

were reviewed and decisions made regarding the requests at the RMSC meetings. Subgroups were chartered to focus on specific areas—eg, anesthesia and pediatric oncology—to ensure that consideration was made for the special needs of those specialties while adhering to the HAMP principles.

**Local Accountability**
Each medical center has a Medication Safety Committee. The committee's responsibility is to ensure HAMP is in place locally and to review trends and local issues for course correction and action. The local committee chairs are invited on a rotational basis to present their local initiatives and issues to the RMSC.

**Measurement**
Initially, the Task Force tracked the percentage of nurses who completed the self-study modules and used observational audits to monitor the implementation of the key HAMP features of independent double-check, use of HAM stickers, special labeling, etc. The Task Force continues to audit but has begun using different methodologies, such as trigger tools, to determine the best way to ensure compliance and identify areas of concern.

**Results**
Outcomes from the regional RRF data have shown meaningful improvements. RRF data was analyzed using the control chart methodology in which one determines whether variations from the mean are caused by a "special cause," in this case, the implementation of HAMP. The RRF data showed 23 favorable special causes that indicate substantial improvement in our volumes of employee-reported medication events and HAMP events (Figure 2). A powerful indicator of improvement is the *Days between Major Injury and Death from All Medication Events* control chart. Through these measurements, we know we have sustained a new and improved process with a new mean. Before July of 2006, events were identified on the average every 13.2 days (Figure 3). As of November 30, 2007, it has been 232 days since an adverse medication event that caused harm.

**Conclusion**
When displaying the data for 2006 forward, a clear trend emerged. The control chart for *Days between Major Injury and Death from All Medication Events* showed a mean of 13.2 for the first six months and increased to 232 days as of November 30, 2007 between event-related major injury and death. A limitation of this data is that this dramatic improvement conclusion is dependent on ensuring that there are no changes (such as reductions) in reporting practices at our 19 medical centers and that the data entry for this time period is complete.

The HAMP uses standardization as the keystone to implementation, maintenance of patient safety gains, and monitoring of policies, procedures, and staff practice. Inpatients, outpatients, and home health patients are all protected under the policy and each practice area is monitored for compliance on a regular basis. The standardized HAM list is the same for all areas of practice and it is mandated that all additions and changes to the program be facilitated through the KPNC RMSC. This standardization is being carried forward by its incorporation into KP HealthConnect, the electronic medical record system. Work with KP HealthConnect teams continues to bring the standardization of medications and documentation strategies to the electronic medication administration record.

Because the ability to transfer practices within and across regions is of such importance for KP facilities, regional toolkits were a major design factor in planning and implementing the HAMP activities to our local medical centers. These kits contain administrative policies and procedures, education and training materials and validation tools, staff competencies and documents with frequently asked questions. Standardized monitoring tools with consistent reporting templates continue to be used to ensure that progress is consistent across the region and outcomes can be measured accurately. These toolkits and monitoring guidelines are a primary driver to ensure the portability of HAMP practices across KP. HAMP has been implemented in all of the KPNC medical centers and is in the process of being implemented in all regions. There is a very strong commitment by the members of the HAMP leadership team to provide help and guidance to other regional HAM groups.

**Key Success Factors**
As the Northern California HAMP program is spread to other regions it is important to keep in mind several factors that were key in the success of the program. These include:
- Top leadership support including visible articulation of the importance of the program and active participation in planning meetings
- Involvement of labor partners and CNA
- Standardized HAM list, education/training, measurement, and tools

When data showed that nurses were still not doing the 5Rs, … the three major reasons were identified: interruptions, distractions, and rushing.
Program sustaining activities such as the monthly HAMP call
- Involvement of CNA QLs in developing programs to mitigate/eliminate issues such as distractions and interruptions
- Regular reports to all levels of the organization that summarize the findings from data.

Next Steps for KPNC

Sustaining the program over time is of utmost importance. A proposal has been developed for 2008 that includes further involvement of the Medical Center Medication Safety Committees in maintaining the program. We are working with the IHI to customize trigger tools for those HAM that have been identified as the most prone to error. These include heparin, insulin, and opiates. A video has been developed through collaboration with the QL nurses that includes the appropriate methods for performing independent double-checks. This has been identified as a particularly difficult issue in implementation. This video will be utilized for training purposes throughout KPNC as will an updated standardized tool for assessing nursing competencies.

Disclosure Statement

The author(s) have no conflicts of interest to disclose.

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The Right Dose

All substances are poisonous, there is none which is not a poison; the right dose differentiates a poison from a remedy.

— Paracelsus (Theophrastus Philippus Aureolus Bombastus von Hohenheim), 1493 – 1541, Swiss alchemist, physician, astrologer, and general occultist