The widespread use of pharmacotherapy in long-term care settings provides opportunity for medication errors (Carfiero, 2003; Gurwitz et al., 2000; Gurwitz et al., 2005; Handler et al., 2007). Gurwitz et al. (2005) estimate that 58% of nursing-home medication errors go unreported and that more than half are preventable. Protecting patients requires analysis of errors and proactive changes to prevent them in the future.

In a punitive practice environment, however, underreporting of medication administration errors and near misses stifles such analysis and proactive change. Confusion about language and reporting requirements of multiple regulatory bodies that oversee the operations of nursing homes and nursing practice combined with a better-safe-than-sorry attitude can lead to formal complaints and investigations, even though a quality assessment and systems-change process might better serve the goal of patient safety.

To clarify reporting requirements and promote quality improvement, the Massachusetts Board of Registration in Nursing envisioned a nonpunitive, facility-based alternative to its complaint resolution process. This alternative arises from certain types of medication errors that are voluntarily disclosed by nurses to their nursing-home employer. Seeking a collaborative approach to the design and implementation of this alternative, the Board developed partnerships and created a regulatory alliance focused on improving quality and patient safety. This article describes how the Alliance is structured and reports on one of its completed activities, an environmental scan, completed using survey research methods. The results depict Massachusetts nurses' voluntary disclosure of medication administration errors, and the nursing homes' patient-safety culture.

Improving Quality

Changing from a punitive approach to errors represents the biggest health-care system challenge (Institute of Medicine, 1999). A nonpunitive approach, in which errors are treated as opportunities for improvement and harm reduction, is one property of a patient-safety culture, a practice environment that balances the need for reporting errors with the need for disciplinary action (Handler et al., 2006; Sammer, Lykens, Singh, Mains, & Lackan, 2010). This balance at the practice level must be cultivated and supported at the regulatory level. (See Table 1.)

Studies indicate that both regulatory climate and nursing-home culture contribute to the under reporting of medication administration errors (Handler et al., 2006; Walshe & Shortell, 2004). Underreporting prevents analysis and correction of both the underlying practice and systems-related causes (Potylycky et al., 2006). Root-cause analysis, practice remediation, and systems change when adopted into nursing-home practice and supported from the regulatory community can be sustainable supports for a just culture (Sammer et al., 2010).

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Nurses’ fear of blame following a medication event and confusion about the error-reporting requirements of multiple regulatory bodies that oversee nursing practice and nursing home operations can stifle the discussion and analysis of medication administration events to promote patient safety. The Massachusetts Board of Registration in Nursing and the University of Massachusetts Medical School Center for Health Policy and Research convened the Massachusetts Medication Safety Alliance, a 15-member collaborative of regulatory agencies and long-term care providers, to develop the Nurse-Employer Medication Safety Partnership Model to cultivate a safety culture in Massachusetts nursing homes that supports voluntary medication-event recognition and disclosure by nurses. A proactive approach to the Board’s public protection mission, the model will promote public safety through early intervention and quality improvement. To guide the model’s development, the Alliance assessed the perceptions of 1,286 nurses working in 109 Massachusetts nursing homes, finding more than half rated their practice environment as punitive and identified fears of blame, disciplinary action, and lawsuits as barriers to medication-event reporting.

Promoting and Regulating Safe Medication Administration in Nursing Homes
Regulatory Partners

The Massachusetts Board of Registration in Nursing understands that efforts to emphasize quality improvement over individual blame depend on a nurse’s willingness to disclose errors voluntarily to his or her nursing supervisors. Needing to understand nurses’ perceptions of the barriers to medication-error reporting and the patient-safety culture in Massachusetts nursing homes and seeking to encourage nurses to report such errors, the Board engaged the University of Massachusetts Medical School Center for Health Policy and Research to develop the Massachusetts Medication Safety Alliance.

The Alliance, a 15-member collaborative of state and federal regulators, other state agencies, and professional associations, is charged with planning a new model of regulatory practice. (See Figure 1.) Networks of regulatory boards, state agencies, and health-care provider organizations are important for establishing communication, exploring mutual interests, and identifying support. However, a different level of collaborative integration is needed to support a change in regulatory practice that promotes transparency and accountability regarding the cause and remediation of medication administration errors, as the Board envisions. To assess nurses’ perceptions of the barriers to medication-error reporting and the patient-safety culture in nursing homes, the Alliance, through its survey workgroup, conducted an environmental scan of a representative sample of Massachusetts nurses, as described below.

Methods

Survey Instrument

The Survey Workgroup chose to administer a three-part instrument, including two previously developed and validated instruments, Determining the Barriers to Medication Error Reporting in the Nursing Home Setting (Handler et al., 2007) and the Nursing Home Survey on Patient Safety Culture (NH-SOPS). The first instrument includes a 20-item scale rated twice by respondents as how likely the item is to be a barrier, and the likelihood that the item is modifiable (Handler et al., 2007). Items that are both likely or very likely to be barriers and are both likely or very likely to be modifiable are identified as immediate action items.

NH-SOPS was designed by the Agency for Healthcare Research and Quality (AHRQ) in 2008 as a diagnostic tool to assess the status of patient-safety culture in a nursing home, to raise staff awareness about patient-safety issues, to evaluate the impact of patient-safety improvement initiatives, and to track changes in patient-safety culture over time (Sorra et al., 2008). The NH-SOPS has 42 survey items measuring 12 domains of patient-safety culture. To compare the results of the Massachusetts study with benchmark data, the responses of the 531 nurses in the national pilot sample, the Center used the NH-SOPS scoring methods, which are publicly available.

Results

Response Rates and Demographics

Of the 3,272 surveys distributed to 110 homes, 1,286 were returned from 109 homes. Response rates for the 109 homes ranged from 10% to 90%, with an average of 41.4%. Less than

Study Participants and Settings

The participants were 1,286 nurses working in 109 licensed nursing homes operating across Massachusetts. To control for the varying number of beds, three nursing-home-size categories were defined as follows: small homes (1 to 49 beds), medium homes (50 to 149 beds), and large homes (150+ beds). In all, 141 were contacted, and 110 assented, for a recruitment rate of 78%. The University of Massachusetts Medical School Institutional Review Board and the Massachusetts Department of Public Health Human Research Review Committee each reviewed the study and deemed it exempt.

Survey Administration

A survey project champion at each nursing home provided the number of nurses employed and received and distributed the survey packets. Each survey packet contained a cover letter, a copy of the instrument coded to match the nursing home, a frequently-asked-questions sheet, a $5 coffee-shop gift card, and a pre-addressed return envelope coded to match the nursing home.

Patient-Safety Culture in Nursing Homes

The biggest challenge to promoting safe-medication practices is creating a patient-safety culture because practitioners fear punitive action from licensing bodies (Institute of Medicine, 1999; Institute for Safe Medication Practices, 2005). A patient-safety culture has these key elements:

- Leadership
- Teamwork
- Evidence-based practice
- Communication
- Learning
- Just culture that promotes accountability and a nonpunitive response to mistakes (Sammer, Lykens, Singh, Mains, & Laikan, 2010)

A clear agenda for nursing-home research is the role of directors of nursing and nursing leaders in creating a practice environment where open and accurate communication can be accomplished (Scott-Cawiezell & Vogelsmeier, 2006). Though the Massachusetts Board of Registration in Nursing’s mission is to protect patients by regulating individual nurse’s practice, the Board also collaborates with other regulatory agencies that have oversight of nursing homes to cultivate a regulatory environment that reduces nurses’ fear of blame for medication errors.
Each workgroup has a distinct purpose.

- The survey workgroup conducted an environmental scan, using an anonymous survey of nurses practicing in randomly selected Massachusetts nursing homes, to assess the patient-safety culture and to identify the barriers to medication-error reporting and the modifiability of those barriers.
- The regulatory alignment workgroup aligned the regulatory requirements regarding the reporting of medication errors by Massachusetts nursing homes to promote a common focus on patient safety.
- The nurse-employer safety partnership workgroup is assessing the culture of safety curriculum and toolkit that it developed to encourage medication-error reporting and root-cause analysis, using the model to promote patient safety through continuous quality improvement.

1% of the surveys had missing information in the NH-SOPS section, with no identifiable pattern of missing information.

Demographics of the respondents follow:

- 74% describe themselves as licensed nurses.
- 78% work directly with patients.
- 65% have worked in their current facility between 1 and 10 years.
- 55% have worked in their current facility for 5 years.
- 21% have worked in their current facility for 11 years or more.
- 51% work 25 to 40 hours a week.
- 31% work more than 40 hours a week.
- Less than 1% are temporary or agency nurses.

Barriers to Medication-Error Reporting

Responses confirmed a direct and positive relationship between patient harm and nurses’ reporting behavior. Although 98% of respondents usually or always report an error that causes harm to a patient, only 42% usually or always report an error that is caught and corrected before it reaches or affects the patient. Of the respondents, 52% seldom or never report an error that is caught and corrected before it reaches or affects the patient, but only 1% seldom or never report an error that causes harm to a patient. Even though 38% reported no errors in the year before the survey, 90% agreed that anyone who is aware of an error should report it.

The five items identified for immediate action, based on their likelihood to be a barrier (first %) and to be modifiable (second %) were as follows:
1. Fear of disciplinary action (60%, 57%)
2. Fear of being blamed (60%, 46%)
3. Fear of liability or lawsuits (58%, 42%)
4. Lack of recognition that a medication error occurred (57%, 64%)
5. Lack of an anonymous error-reporting system (55%, 65%)

Patient-Safety Culture in Massachusetts

Respondents rated the 12 domains of patient-safety culture in their settings. The mean of positive response scores exceeded 50% for all but two domains, staffing (49%) and nonpunitive response to mistakes (40%). Two other domains, compliance with procedures (57%) and communication openness (51%), had scores between 50% and 60%. Scores for the remaining domains ranged from 62% (handoffs) to 91% (overall perceptions of resident safety). Table 2 shows the scores for all 12 domains and the overall rating for patient safety.

To understand the nonpunitive response to mistakes domain score more fully, the workgroup examined the item responses. Most nurses (56%) agreed or strongly agreed that staff members are afraid to report their mistakes. Only 57% agreed or strongly agreed that staff members feel safe reporting their mistakes, yet 56% agreed or strongly agreed that staff members are treated fairly when they report mistakes.

Comparison to Nurses in National Pilot

The mean percentage of positive response scores for the Massachusetts sample was significantly lower than scores from the national sample in four domain areas:
- Compliance with procedures (57% vs. 69%)
Training and skills (63% vs. 69%)
Nonpunitive response to mistakes (40% vs. 56%)
Communication openness (51% vs. 58%)

Significance was tested using the standard error of proportions test for two independent samples.

Discussion
Challenges Identified
The difference between Massachusetts nurses and the AHRQ national sample regarding the nonpunitive response to mistakes suggests that this domain is an immediate-action item. The domain rating suggests that the current practice environment in Massachusetts nursing homes of all sizes may not be conducive to the disclosure of medication administration errors or near misses.

Fewer than half of the respondents rated their work environment as nonpunitive, and more than half identified fears of blame, disciplinary action, and lawsuits as barriers to reporting medication events. Implementing a nonpunitive approach may reduce the number of nurses who fear a punitive response to disclosure, report no events in a given year, or fail to report events of low scope and severity. Errors caught and corrected before reaching a patient and those causing minimal harm to a single patient are included in the criteria, and the Board seeks to promote discussion of these situations through creation of a supportive regulatory environment.

About one-third (37%) of respondents reported that staff members feel safe when they report mistakes. Teamwork, systematically developed and monitored by nursing directors in nursing homes as they form communities of practice, provides the basis of the Alliance’s strategy to promote practice environments in support of communication openness, where nurses feel safe to discuss adverse events. Educating directors of nursing to systematically promote teamwork (Gajda & Hurton, in press) and discussion of medication events is an important component of the Alliance’s nonpunitive, nursing home–based, education-oriented model.

Strengths Identified
Because 90% of nurse respondents agree that errors should be reported, Alliance members are encouraged that reporting will improve in a supportive environment. Positive responses about teamwork, feedback and communication about incidents, and organizational learning suggest that the industry will accept a nonpunitive model.

Further, respondents consider the lack of an anonymous reporting system to be modifiable. Though not anonymous, the model promotes a safe-practice environment in which nurses can openly discuss mistakes and participate in the development and implementation of quality improvement plans for nursing practice remediation and systems change.

<table>
<thead>
<tr>
<th>Patient-Safety Culture Domains (number of responses in Massachusetts survey)</th>
<th>Positive Responses in Massachusetts survey</th>
<th>Positive Responses in AHRQ survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teamwork ((n = 1,220))</td>
<td>66%</td>
<td>67%</td>
</tr>
<tr>
<td>Staffing ((n = 1,163))</td>
<td>49%</td>
<td>46%</td>
</tr>
<tr>
<td>Compliance with procedures ((n = 1,164))</td>
<td>57%</td>
<td>69%</td>
</tr>
<tr>
<td>Training and skills ((n = 1,217))</td>
<td>63%</td>
<td>69%</td>
</tr>
<tr>
<td>Nonpunitive response to mistakes ((n = 1,116))</td>
<td>40%</td>
<td>56%</td>
</tr>
<tr>
<td>Handoffs ((n = 1,234))</td>
<td>62%</td>
<td>64%</td>
</tr>
<tr>
<td>Feedback and communication about incidents ((n = 1,237))</td>
<td>87%</td>
<td>87%</td>
</tr>
<tr>
<td>Communication openness ((n = 1,221))</td>
<td>51%</td>
<td>57%</td>
</tr>
<tr>
<td>Supervisor expectations and actions promoting patient safety ((n = 1,228))</td>
<td>91%</td>
<td>88%</td>
</tr>
<tr>
<td>Overall perceptions of resident safety ((n = 1,253))</td>
<td>91%</td>
<td>88%</td>
</tr>
<tr>
<td>Management support for resident safety ((n = 1,187))</td>
<td>71%</td>
<td>70%</td>
</tr>
<tr>
<td>Organizational learning ((n = 1,169))</td>
<td>73%</td>
<td>75%</td>
</tr>
<tr>
<td>Overall ratings ((n = 1,267))</td>
<td>84%</td>
<td>88%</td>
</tr>
</tbody>
</table>

Significance was tested using the standard error of proportions test for two independent samples.

Perhaps most encouraging is the high percentage of Massachusetts nurses who respond positively about their perceptions of resident safety. Clearly, practitioners and regulators share the goal of patient safety.

The survey provides the most complete information available to date on nurses’ ratings of the barriers to medication-error reporting and the patient-safety culture in Massachusetts nurs-
ing homes and reveals important findings in the nonpunitive response to mistakes domain.

Limitations

Our ability to sample nurses was limited by the lack of a master sampling frame. The sampling design reduces, but does not eliminate selection bias. We were not able to control for the means by which these homes were located in various regions, for example, nor were we able to control for the hiring decisions of these facilities. Finally, we relied on a survey project champion in each nursing home to administer the survey, resulting in each champion using a slightly different approach to survey distribution. Sometimes, the champion distributed and then collected the survey instruments, which may have influenced nurses’ willingness to respond.

Model Development

The Alliance used the assessment data to develop the model prototype that uses home-based, nurse-employer, partnership teams. The director of nursing will convene meetings to conduct an education-oriented root-cause analysis of medication events that meet the approved criteria and are reported by nurses. Using the model, the teams will analyze medication events with a range of patient-harm outcomes, including events in which harm did not reach the patient and those that resulted in minimal harm but did not seriously affect the health and safety of the patient and were isolated to only one patient. Based on their analysis, the teams will implement quality improvement plans for nursing practice remediation and system change.

To support the teams, the model will also include a nonpunitive, culture-of-safety continuing education program that directors of nursing will complete; a medication event reporting toolkit for use by nursing service leaders; and a learning network for sharing lessons learned among nursing homes. This model will promote public safety through early intervention and quality improvement when a medication-event meeting the criteria is reported to the nursing director. Currently, the Alliance is systematically planning for a limited pilot of the model in a selected group of Massachusetts nursing homes.

Summary

The Alliance wants to encourage nurses to report medication administration errors voluntarily, and a nonpunitive response to such reports can encourage this behavior. Results of the environmental scan, however, indicate that fewer than half of the nurses in nursing homes perceive a nonpunitive response to mistakes. The Alliance will address this challenge by exhibiting and promoting collaboration and by cultivating the commitment of senior leadership in nursing homes.

The measured strength of the Alliance will assure that a nonpunitive corrective action plan and shared learning will result when nurses disclose adverse events. Inviting fellow regulators to plan, design, and implement the new model allows each regulatory stakeholder to be a full partner with the Board to this effort to align its current regulatory processes with the new model to identify potential risks. Aligning regulatory practices is important for each regulatory agency to share its commitment to patient safety, which can be leveraged to engage the nursing-home owners and administrators in the subsequent phases of the model’s development and adoption.

References


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