Risk Models to Improve Long-term Care Medication Safety

Principal Investigator: Grant Higginson, MD, MPH

Team Members: Sharon Conrow Comden, Margaret Murphy Carley, Megan Hornby, Linda Kirschbaum, David Marx, Misti Hale, Joel Young, Lynn Hanson, Thomas Brundage, Pam Ruona

Organization: Oregon Department of Human Services, Office of the Public Health Officer

Project Dates: 9/30/2003-9/29/2004

Federal Project Officer: James B. Battles

This project is supported by Agency for Healthcare Research and Quality
Grant # UC1HSO14259

Abstract

a) Purpose: To determine if sociotechnical probabilistic risk assessment (ST-PRA) can create statewide risk models to identify combinations of medication delivery system and behavioral elements producing wrong drug, wrong dose, wrong resident, and omission medication errors in nursing and community-based care (CBC) facilities.
b) Scope: Long-term care (LTC) providers and state agencies, disappointed by the failure of educational and regulatory interventions to improve medication delivery system safety, designed this study to focus on system risks within the control of nursing, assisted living, and residential care facilities.
c) Methods: This developmental study uses four tools—process mapping, control system mapping, modified failure modes and effects analysis (FMEA), and sociotechnical probabilistic risk assessment (ST-PRA)—to construct risk models. Multidisciplinary teams from a convenience sample of 10 nursing and eight assisted living/residential care facilities created the models with input from pharmacists, community physicians, and state surveyors. A stratified, random sample of 20 nursing and CBC facilities was surveyed to determine if critical elements in the models generally represent medication delivery systems in similar facilities across Oregon.
d) Results: Nursing and CBC risk models were successfully completed. Prescribing and administration errors are the models' dominant risks. Multiple single failure path errors were identified Validation survey data confirmed that 89.1% of selected exposure and error rates in the models were comparable to values from a statewide sample of nursing and CBC facilities. Oregon LTC providers, state agencies, pharmacy companies, and medical providers are collaborating on strategies to address the risks identified in these models.

Key Words: medication error, nursing facility, residential care facility, assisted living facility, geriatrics, long-term care, risk, probability, models

Purpose

To determine if sociotechnical probabilistic risk assessment (ST-PRA) can create statewide risk models that identify combinations of medication delivery system and behavioral elements producing wrong drug, wrong dose, wrong resident, and omission medication errors in nursing and community-based care facilities.

Scope

Background:

Improving the quality and patient safety of long-term care is a continuing concern for policymakers and providers at the national and state levels.[1] The US population is aging, increasing the demand for quality long-term care (LTC).[2] In 2000, 4.5% or 1.56 million seniors 65 or older lived in nursing homes, compared with 18.2% of seniors over 85.[3] Persons over the age of 65 in both the acute[4] and long-term care settings[5] are at high risk for preventable adverse drug events (ADEs). Thomas and Brennan report almost a four-fold difference in the rates of hospitalized patients 64 and younger (0.17/100 discharges) compared with those 65 or older (0.63/100 discharges, $P<0.05$). Several studies have documented the frequency of ADEs in long-term care facilities, but the literature is plagued with methodological differences that make generalizations difficult.[5,6,7] Gurwitz and his colleagues report that, of 276 preventable ADEs detected in their nursing home study, 170 or 61% were serious or life threatening.[6] Wrong dose errors are the most frequent causes of ADEs in both hospitals[8] and nursing facilities. In one study of 18 nursing homes, 68% of the errors leading to adverse events occurred during the ordering stage, and almost two thirds were wrong dose errors.[6]

The hospital literature provides a much larger and more complete picture of the relative frequency and significance of wrong drug, dose, patient, and omission errors. Barker et al.'s benchmark observational study of medication administration errors in 36 hospitals and nursing facilities found no significant error rate differences between these two types of facilities.[9] Appendix A contains tables summarizing published or calculated rates from studies of each type of error in standardized rates per 1000 by stage—prescribing/ordering, transcription, dispensing, and administration by potential for harm (Table 1) and frequency of error (Table 2). (Note: the incidence/1000 format permits cross-study comparisons and comparisons with the probability models generated by this study.) The following are reasonable generalizations drawn from the six studies profiled in the tables:

- Wrong drug—much less common and less often clinically significant than dose errors
- Wrong dose—most frequent and highest rate of clinical significance
- Wrong resident—resident gets someone else's drugs; high potential for harm but very low frequency
- Omission (omitted dose)—very high frequency but low rate of clinical significance

Overall, wrong drug medication administration errors (6.8/1000 doses) are more frequent than wrong drug prescribing errors (2.7^{10}-3.2^{11}/1000 orders). Wrong dose errors are predominantly prescribing (7-9.3/1000 orders—over- and under-dosing) and administration errors (38/1000 doses). There are very little data on wrong resident/patient errors in the literature; prescriber, pharmacy,[12] and administration[13] all contribute. Omission errors occur predominately during medication administration—56.9/1000 doses. Transcription errors are an important contributor to medication errors,[14] but

relatively few studies use a rate/1000 order format. One study reports a rate of 4.8/1000 transcription errors for handwritten prescriber orders—typically how orders are communicated in LTC[15]—but does not report the types of medication errors resulting from these transcription errors. Prescribing and administration errors are the most common causes of adverse drug events, but, with few exceptions,[13,16] most studies provide high-level descriptions of the systems and causal factors behind errors.

In the late 1990s, Oregon's state agency responsible for regulating nursing and CBC facilities—Seniors and People with Disabilities (SPD)—and the Oregon Health Care Association (OHCA; the LTC provider association), began jointly developing and sponsoring quality improvement and educational activities to address a range of LTC problems. Medication administration citations were the top regulatory issue, so improving medication administration practices was a primary focus for this partnership. Despite these efforts, state surveyors continued to identify large numbers of low-impact deviations from medication administration process standards. In 2002, Oregon regulators cited 16.6% of nursing facilities (NFs), 34.2% of assisted living facilities (ALFs), and 52.7% of residential care facilities (RCFs) for medication-related issues during state licensing surveys. Over 90% of ALF/RCF citations were rated Level 2 (i.e., minimal harm that does not affect resident's quality of life or physical functioning).[17]

In 2002, a group of long-term care pharmacies, OHCA, the Alliance (a smaller LTC association), educators, and SPD met to discuss the declining compliance and medication safety overall. An unexpected result was an agreement that better training was not the answer. The group agreed to shift its vision to improving safety rather than compliance. Early in 2003, the LTC group partnered with public health to explore how sociotechnical probability assessment (ST-PRA) methodology[18] might help them identify the combinations of operational systems and behavioral events leading to the four leading medication errors: wrong drug, wrong dose, wrong resident, and omitted drug/dose. There are several advantages to using ST-PRA to develop medication system risk models for nursing facilities and CBC (ALF/RCF) facilities:

(1) Rapid assessment and improvement potential: Models can incorporate the cumulative knowledge of operations experts when complete data sets from other sources are not available.[19]
(2) The medication administration delivery system is very complex; by modeling the unique combinations of events, processes, and behaviors that increase or decrease risk, objective evaluation and comparison of different configurations are possible.[20,21]
(3) The models can inform decision making—at a local and a policy level—because ST-PRA can identify immediate high-impact changes and model different interventions to identify the variation with the most benefit.[22]
(4) Having a shared model facilitates the safety culture: Providers, managers, pharmacists, prescribers, staff, and regulators can see their roles in the error process, their interdependencies, and how their actions increase or decrease risks for each other and, ultimately, for patients.[19,20,21]

Settings:

Oregon, long an innovator in how services to seniors are delivered and financed, licenses 150 nursing homes in 32 of its 36 counties, with an average size of 89 licensed beds.[23] Oregon facilities serve a patient population similar in most respects to the rest of the US but with fewer staff.[24] Oregon licenses 191 assisted living facilities (average bed size=66) that provide an alternative to institutional care for people who are unable to live independently.[23] All provide room and board and some level of service, including medication management, assistance with activities of daily living, and planned activities. Assistance with medications is the fastest growing type of personal service in ALFs; 76% of residents use this service.[25] There are 236 licensed RCFs in Oregon (average bed size=36) serving six or more residents.[23] All provide room and board and some level of service, including medication management, assistance with activities of daily living, and planned activities. For the purposes of this study, community-based care includes assisted living/residential care facilities and excludes board and care homes. The scope of this study is limited to ALFs and RCFs with 20 or more beds.

Participants:

Six volunteer LTC chains identified 18 of their 54 facilities to participate in the modeling phase of this study. These facilities were mostly urban, although at least four were located in rural areas at some distance from urban centers. They received pharmacy services from four large contract pharmacy companies, and all belonged to the Oregon Health Care Association.

Methods

Design:

This is a prospective, developmental study using process mapping, control system mapping, failure modes and effects analysis (FMEA), and sociotechnical probabilistic risk assessment (ST-PRA) to produce medication delivery system risk models. Unlike traditional single facility probabilistic risk assessments, this project built the models using seven chain-specific, multidisciplinary modeling groups representing 18 facilities belonging to six LTC chains. After the NF and CBC models were complete, an onsite validation survey was designed, pre-tested, and completed in a statewide, randomized, stratified sample of nursing and CBC facilities. The survey collected data to evaluate whether process, behavioral, and

structural elements found in the models reasonably represent the medication delivery processes in Oregon NFs and CBC facilities.

ST-PRA Model Building

Nursing Facilities Sample: Facilities participating in the NF model building were drawn from a volunteer, convenience sample of four large Oregon LTC chains, with 10 facilities selected from both urban and rural locations. Bed size ranged from 88 to 214 licensed beds; the average was 120 beds, which was somewhat higher than the statewide average of 89 beds. This is probably attributable to the fact that many of the facilities are located in urban areas, where bed size tends to be higher.

Community-Based Care (ALF/RCF) Facility Sample: The CBC convenience sample of five ALFs and three RCFs was drawn from 48 facilities owned by four large chains. ALF/RCF bed size ranged from 60 to 122, averaging 73 beds—again, somewhat larger than the statewide combined ALF/RCF average of 50 beds. This shift is also likely due to the higher proportion of urban facilities in the sample.

Group Composition and Content: From one to two modeling group participants were recruited from each facility using a noncoercive protocol approved by the state's Public Health Institutional Review Board. Protecting participants from any type of repercussion stemming from their critical and candid assessments of safety risks was a high priority. Aside from ethical concerns, if group members believed they could not be completely open in the modeling groups, the content and accuracy of the models would be compromised. No identifiable adverse events or medication errors were discussed in these groups, both to protect resident privacy and to ensure that Oregon's mandatory reporting requirements would not be breached. Charge nurses, staff nurses, and certified medication aides (CMAs) participated in the NF model-building groups. Staff participating in the CBC modeling included full- and part-time nurse consultants, residential care managers (very experienced caregivers promoted into first-line management), lead caregivers functioning as medication aides (no certification required), and caregivers with medication administration responsibilities. Initially, each chain had its own modeling team that met four times, both to encourage open communication and to capture important chain-specific process variations. The groups did not include personnel with direct supervisory relationships to each other, to encourage frank and complete discussions.

Modeling groups were held separately for prescribers (MDs/DOs/GNPs) and for pharmacy consultants representing four large contract pharmacies, to encourage their candid input into the NF and CBC models. The modeling sessions were lively, and the participants normally were quite forthcoming.

Model-Building Process

A detailed description of the model-building process has been published elsewhere.[19,26] The following is a very high-level overview of the ST-PRA modeling process.

Step 1 — Identify the "Top-Level" Event (wrong drug, dose, resident, omitted drug/dose). See Model Parameters section.

Step 2 — Use Modeling Groups and the Process Failure Modes and Effect Analysis to identify Individual Failure Modes and Failure Rates. Beginning with an undesirable outcome or top-level event (wrong drug, dose, etc.), each modeling team developed preliminary process maps representing medication delivery processes under the direct control of the facility (processing prescriber orders, transcription, receipt/storage of delivered drugs, medication administration) for each of the four types of errors being studied. Groups then began control process mapping, identifying active controls and the features of the system in place specifically to help manage the risks of the undesirable outcome under analysis. Once the process and control system maps were complete, the modeling teams began to identify individual failures (errors, at-risk behaviors, systems, and equipment failures) that could lead to the undesirable outcome under analysis, using an abbreviated FMEA analysis. The FMEA provides the source data for building the initial risk trees (Table 1).

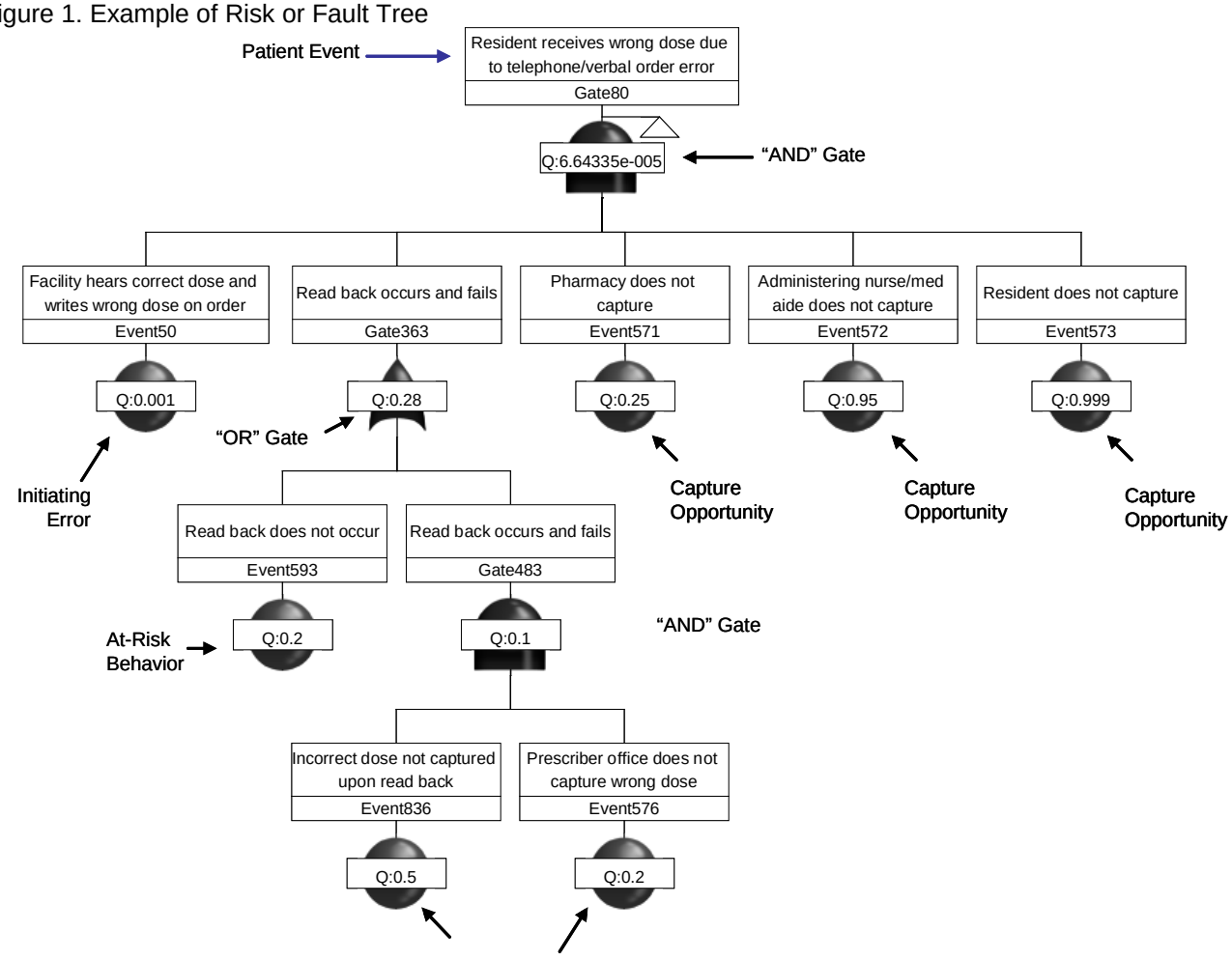
Table 1. Examples of Summary Failure Modes and Effects Analysis (FMEA)

Process	Failure Mode	Downstream Controls	Failure Effect
In-Room Patient Identification	Nurse enters wrong room	Visual identification of patient • Arm band check • Verbal name check • Verbal discussion of medication with patient	Medication delivered to wrong patient (note: ST-PRA will model failures of downstream controls that might capture nurse entering wrong room before medication reaches the wrong patient)
Physician Ordering	Medication order written in wrong chart	Nurse review of order Pharmacy review of order Verbal discussion of medication with patient	Medication administered to wrong patient (note: ST-PRA will model failures of downstream controls that might capture the physician error before reaching the patient)

Modeling teams were able to discuss noncompliant or “at-risk” behaviors and begin to identify the impact of these deviations on medication error risks. LTC nurses, aides, and caregivers often administer the same drugs to the same patients for years. Routine “shortcuts” occur when they don’t perceive adverse consequences or when they minimize the risks associated with deviations from policy. In the groups and by secret ballot, team members reported rates of noncompliance for checking the MAR before giving medications to familiar residents and began to see how this practice influenced each of the four errors under study. Borrowing medications from one resident’s supply to sustain treatment for another resident when the critical medication (often antiseizure, cardiovascular, or antibiotic drugs) is not otherwise available is another “at-risk” or noncompliant behavior. This practice is generally forbidden in most policies and procedures, but this study found that it occurs with some frequency, often to cope with circumstances outside the staff’s control—for example, a dose or drug is not stocked in the emergency box, and the pharmacy is not able to deliver it in time to avoid serious consequences to the resident’s health.

Step 3 — Build the risk models or fault trees. Consolidate NF and CBC chain models into two individual models. Figure 1 illustrates a typical fault tree.

Figure 1. Example of Risk or Fault Tree



The top-level event in this fault tree is a resident receiving a wrong dose due to a telephone verbal order error. This event itself represents a subset, or branch, of the wrong dose tree. Below the top-level event is an “AND” gate, meaning that all events below the gate are required to satisfy the condition above the gate. In this model, the initiating error is that the facility hears or writes the wrong dose on the order. To make it to the resident (the top-level event), the read back must fail and the pharmacy, administration, and the resident also must miss the error.

Gate 363 is an “OR” gate, meaning that only one of the conditions below the gate is required to satisfy the condition above the gate. In this case, the read back fails when either the read back does not occur (the at-risk behavior) or the read back occurs but an error in the read prevents the initiating error from being caught. ST-PRA models contain a number of potential elements (Table 2, below).

Table 2. Risk Tree Elements

Risk Tree Element	Description
Basic Event	The basic building block of the tree. Examples include a human error, an equipment failure, an exposure rate, or a capture opportunity.
Exposure Rate	Exposure rates are used as modifiers for branches of a tree to reduce the contribution of a tree that does not occur in every case of medication delivery. As an example, at a high level, the models were split and modified by exposure rates between injectable and oral medications.
Undeveloped Event	Undeveloped events represent a combination of failures that were not developed in the model that that do not indicate a single breach of a duty (human error or at-risk behavior). Essentially, the undeveloped event is an intermediate outcome put into the tree without being broken down into its component errors.

A number of elements reside within the basic events of the risk tree that reveal the strengths and weaknesses of the medication delivery process. These are included in Table 3.

Table 3. Failure and Recovery Elements in Risk/Fault Trees

Risk Tree Element	Description
Human Error	The most fundamental basic event in an ST-PRA risk tree. Human errors can be defined as an inadvertent breach of a duty. Examples include: • Physician orders wrong dose • Nurse fails to detect error on physician order
At-Risk Behavior	An at-risk behavior is a knowing deviation from procedure. Examples include: • Nurse does not conduct review of MAR • Medication aide does not remove discontinued medications from bin
Equipment Failure	Any equipment failure that can affect the top-level event. An example in this model is: • Fax transmission failure
Capture Opportunities	Capture opportunities refer to those activities that either actively or passively detect and correct the initiating error. Failed capture opportunities are represented in the tree by either a human error or an at-risk behavior. Examples include: • Nurse fails to detect wrong dose • Pharmacist does not detect wrong dose It is important to note that many missed capture opportunities do not represent a human error but instead merely the opportunity catch an upstream mistake that was not realized (e.g., resident not capturing wrong dose).
Active Controls	An active control is any feature of the system design that is specifically intended to reduce the risk that is being modeled. Examples include: • Blister packing of medications • Second check of MAR transcriptions
Passive Controls	Passive controls refer to those system features that, though not specifically in place to reduce risk, nevertheless act to reduce the risk being modeled. Examples include: • Color of pill • Resident detection of wrong pill

Step 4 — "Reality Test" the Risk Assessment Models:

Use any and all data that can be found to aid the model-building teams. This data can come from

- Mishap data from literature and other sources
- Focus group reviews (prescribers, pharmacists)

Chain review sessions with managers

In this research, this step also included the statewide validation survey to ensure that input from the 18 participating facilities would represent a "statewide" model.

Step 5 — Identify Weaknesses and Strengths in the System Design

Step 6 — Identify Potential Risk Reduction Strategies

Step 7 — Update Model to Determine Predicted Effectiveness of Prevention Strategies

- Sensitivity analyses

- Intervention strategies can be evaluated one at a time
- Reduction of risk calculated for each strategy
- Return on investment calculated for each strategy
- Model best and worst case structures to identify critical elements in models

Step 8 — Continuously Update and Evaluate the Model

- Use future mishap data to evaluate accuracy of the model
- Use model to evaluate subsequent changes to system
- Use model to manage risk

Model Parameters:

After the orientation visits to one facility in each of the six chains, the research team established modeling boundaries for the teams, defined the types of medications included in the study, and decided that some important but complex subsystems or processes could not be included in the initial modeling effort.

Boundaries: Each model includes only the processes within the direct control of the facilities. Processes included:

- Prescribers' orders being received (fax, telephone, verbal, brought in by resident, and written orders) and processed by nurses or caregivers
- Transcription of the orders into the chart and/or MAR—and monthly MAR update
- Facility ordering new and refill drugs, receiving, and stocking medications from the pharmacy
- Medication administration

Medications included in the study: The models estimate error rates only for regularly scheduled and prn or "as needed" oral solids, liquid, and injectable medications normally requiring a licensed prescriber. The study excluded vitamins, supplements, OTC drugs, patches, IVs, ointments, drops, and inhalers.

Rates are calculated per first dose given in the models, because probabilities of detection increase with each additional medication pass. Definitions have to accommodate the myriad events that arise at the operations level, and many have both prescribing and administration elements. These top-level events (TLEs) arise from errors made by prescribers, pharmacies, nurses, and/or medication aides at any level of the processes being modeled.

- Wrong drug—resident receives a drug prescribed that is not clinically indicated (contraindicated, known allergy, duplicate therapy) or a drug administered that was not ordered for this resident, including a discontinued (d/c'd) drug that continues to be administered.
- Wrong dose—resident receives a dose or frequency prescribed other than what is clinically indicated or a dose or frequency administered other than what was ordered. Note: If a single dose is missed in a med pass, it is included in the omission model.
- Wrong resident—resident receives one or more drugs intended for another resident.
- Omission—resident did not receive ordered drug or single dose, including because of refusals.

Processes or Variations Not Included in Models:

- New resident admission or readmission
- Resident transfer to or return from emergency department
- Emergency-box errors
- Self-administration errors by residents
- Extra rounds of transcription from scratch paper, faxes, or prescriber orders to permanent chart forms
- Wrong drug form—crushable or not, delayed release, etc.
- Inventory management processes: matching incoming drugs to MAR
- Use of temporary or agency personnel to administer medications

Challenges

This project is ambitious and methodologically messy. PRAs typically profile single facilities or plants, although there may be multiple divisions or departments involved in processes being modeled. The research team had no assurance that processes crossing multiple facility and/or organizational boundaries could be successfully modeled. Supporters of the study (providers, regulators, policymakers) believed the benefits of having well-defined and visible risk models of the four top errors outweighed the potential risks of doing the present study, because this type of information is not available from any other source.

Integration of human factors into probabilistic risk assessment—historically, single case studies of mechanical and procedural failures leading to catastrophic plant or equipment failures—is evolving.[27,28,29] ST-PRA is one approach to incorporating human behaviors and deviations, often neither easily nor precisely quantifiable, into probability risk assessment.[30] In this study, the key building blocks of a risk or fault tree—process maps, exposures, error or failure rates, and capture rates—had to be estimated based largely on modeling group participants' experience in their respective

systems. Patient safety PRAs have to deal with many uncertainties, because most error reporting data are unreliable and rates reported in the literature are often not adaptable for probability modeling purposes. The quality of a PRA begins with the completeness of the fault trees, because there is a high degree of uncertainty and interanalyst variation with PRA probabilities. The modeling groups placed a very high priority on creating accurate and complete descriptions of the critical ordering, transcribing, medication processing, and administration processes in their facilities. PRA analysts will appreciate the difficulties faced by the modeling teams, including but not limited to:

1. Keeping the models at a manageable size—sorting the wheat from the chaff; identifying substantive variations between facilities and including or excluding them during the modeling process.
2. Documenting NF and ALF/RCF rate differences for what turned out to be essentially the same medication delivery systems models; a few branches are unique to NFs or CBCs.
3. Working within very tight time and resource constraints—the facilities could not spare medication staff for more than one half-day every 2 to 3 weeks, so the modeling teams had to be scheduled to accommodate these needs.
4. Consolidating six chain's fault or risk trees into two credible NF and CBC models. It was possible only because:
    - Processes are not unique for each patient; they are largely "rule driven" by the prescriber's medication order(s) and governed by medication administration "standard operating procedures" broadly adopted by the nursing and pharmacy professions and regulators across all three facility types; and
    - Resident populations share a high prevalence of chronic disease; the drug prescribing patterns are similar whether a resident is in an NF, ALF, or RCF.[31,32]
5. Evaluating the models for basic validity—Do the models generally represent medication delivery system processes used across the state? Do the probabilities in the models generally reflect the risks of different top-level events? Three strategies were applied to provide "reality checks" on the models.[19]
    - Successive Rounds of Review During Modeling: This study employs successive rounds of modeling and review to refine the content of the models—almost a modified Delphi process. Model builders had opportunities to see their own work and the work of other groups and suggest changes to it. Managers, prescribers, and pharmacy consultants also had independent opportunities to provide input and revise the models based on their observations of the medication delivery process.
6. Review and Comparison with Published Literature: Medication error studies were analyzed by type of error (wrong drug, dose, patient, and omitted dose) and by stage of error (prescribing, transcription, dispensing, and administration); when possible, rates per 1000 orders or per 1000 doses were calculated to permit limited comparisons with rates in the models. None of the published rates were for first dose delivered, so comparisons between these rates and rates from the model must be interpreted cautiously.
7. Validation Survey: A statewide, random sample of 20 facilities was surveyed to collect prescribing/ordering, transcription, pharmacy ordering and processing, medication receiving and storage, and administration processes data for comparison with data contained in the models.

Creating Order/Dose Rates for the Risk/Fault Trees:

The frequency of each event is expressed in the tree as a probability. In order for modeling team members to estimate rates for events, they must relate their own work experience with a particular event (i.e., "I saw this three times last year") to some standard denominator for the overall frequency of the activity (orders or doses). Denominators may be for periods ranging from a month (to capture frequent events) to a year (for events that happen infrequently).

A random, two-stage sampling frame weighted by facility type (proportion of NF, ALF, RCF licensed beds in the state) and month to avoid seasonality bias was designed to estimate the mean number of orders (new, change, and d/c) and doses (oral solid, liquid, and injectable) from a sample of 2003-2004 NF and CBC MARs. The mean rates are displayed in Table 4.The rates of NF and CBC existing orders, changes processed per month (new, change, d/c), and doses per month were not statistically different. Given the prevalence of chronic disease in both populations, this finding is not surprising.

Table 4. Results of MAR Analysis

	Nursing Facilities	Community-Based Care	(P value)
Sample Size, Number of MARs	40	35	
Mean (SD) Orders at Start of Month	6.2 (2.7)	7.0 (4.0)	0.3094
Mean (SD) Orders (new, change, d/c, temp) Processed/Month	4.4 (7.3)	2.9 (3.1)	0.2582
Mean (SD) Doses of Oral Solids per Month	241(136.8) Range: 81-765	252 (132.6) Range: 53-563	0.7393

VALIDATION SURVEY

Objective:

To determine if the model reflects the medication processes operating in NFs and CBCs (ALFs and RCFs with 20 or more beds) in the rest of the state.

Evaluation Samples:

A three-stage, stratified design drawn from all NFs and ALF/RCF (20 beds or more) facilities in Oregon, proportionally stratified by type of facility (NF or CBC), type of ownership (60% chain/40% non-chain ownership statewide), and location (70% within an MSA/30% not within an MSA), with 5% oversampling. Ten NFs and 10 CBC facilities were randomly drawn, with replacement. Facilities were drawn from facility lists based on the April 2004 state licensing list (less the original 10 NF and eight CBC facilities participating in the model building)[33] using a random numbers table. Three facilities were replaced due to construction, upcoming surveys, or participation in another study.

Ten nursing facilities participated: six chain and four independently operated; six were located in MSAs, and three were outside MSAs. NF bed size ranged from 22 to 115 beds, and the mean size was 69.6 beds (compared with the state average of 89 beds). CBC facilities ranged in size from 48 to 168 beds, and the mean size was 79.7. The statewide average beds for ALF/RCFs with 20 beds or more was 58.2 beds. Smaller NFs and larger ALFs/RCFs were over-represented in the sample. This difference may be an artifact of the small sample. Small samples are especially prone to this type of problem.

Survey Process:

The structured interviews collected data describing the facility (size, chain or independent, etc.); the presence or absence of policies and procedures likely to influence wrong drug, dose, resident, and omission medication errors; use of personnel; respondent's opinions about factors contributing to administration errors; perceived severity of different types of errors, and detailed information about medication orders (how they were processed/transcribed into the chart and MAR, pharmacy ordering and processing, medication receiving and storage, and the medication administration process). Model-building groups had identified the content and display of information in MARs and on medication labels as risk issues, so samples of five MARs and samples of labels from the major pharmacy services were collected. A blind ballot to collect opinions on the frequency that staff check MARs before giving every medication to a resident was collected from each respondent.

Study Design Limitations:

This study is by definition a developmental effort, applying a well-tested methodology to a new set of problems on a very large scale. This was an ambitious effort, given the limited time and resources available. This project is envisioned as the first generation of Oregon LTC risk models; it is understood that the models are "living" in the sense that they will be improved upon and revised as new information becomes available. Given the current limited resources, tight boundaries were imposed on what could be modeled, excluding some important risk prone processes. New resident/patient admissions and transfers between LTC facilities and hospitals/EDs, for example, are two unexplored processes with high levels of medication error risk.[5,34]

Experts generally agree that a PRA model begins with the quality of the fault tree; is it complete, does it represent the important variations or branches contributing to risk, how are uncertainties addressed, are the assumptions and limitations clearly defined?[27,28] Limited data were available to populate these models; most of the risk probabilities were based on expert estimates from the modeling groups. These estimates are subject to various kinds of bias; indeed, perusal of the medication error literature (see Appendix A, Tables 1-2) documents that, although some top level rates are reasonably congruent with findings from other medication error studies, others are very different. Given the circumstances, this is to be expected. PRA models represent an estimate of risk, and most models are never "validated" retrospectively with operational data. It is hoped that public and private LTC organizations in Oregon will find the resources necessary to refine and improve on this work. Findings of this study may not be generalizable if the models are missing important medication systems process elements, either because of sampling bias or because of the decision to include or exclude variations that were identified during the initial model-building process.

Results

This study produced one risk model for nursing facilities and one for community-based care (ALFs/RCFs). The fault or risk trees describe the events and combinations of events leading to four top-level events or errors. The models identify from 840 to 940 separate events and from 32 to 58 different failure paths for each type of error. These risk models are prospective, predictive risk models: they predict the likelihood of top-level events. They speak to the future: what will be the rates of medication events with the system as-is? Table 5 shows the results of these risk models, extrapolated to represent the risk to an average resident over 1 year in either a nursing facility or a community-based care facility.

Table 5. Nursing and Community-Based Care Facilities: Events Per Resident Year

Model	Nursing Events Per Resident Year	CBC Events Per Resident Year
Wrong Drug	5.9	7.0
Wrong Dose	2.8	2.8
Wrong Resident	1.0	0.7
Omission	70	70

Wrong Resident:

Figure 2. Top-Level Risk – Wrong Resident – Nursing Facility

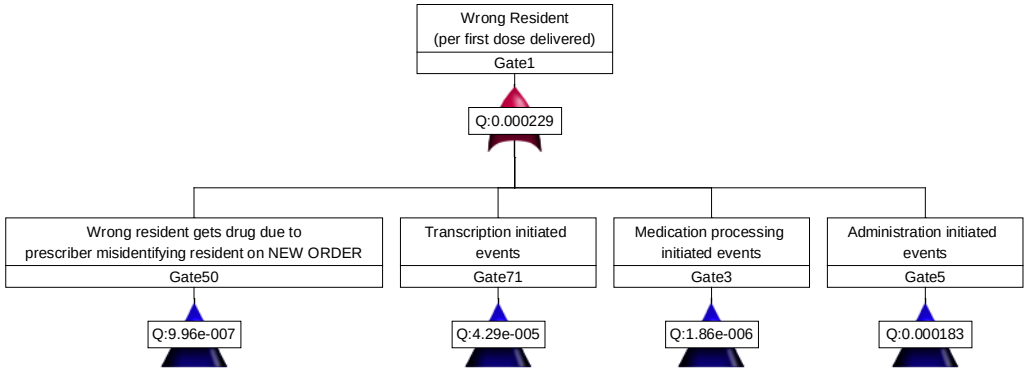
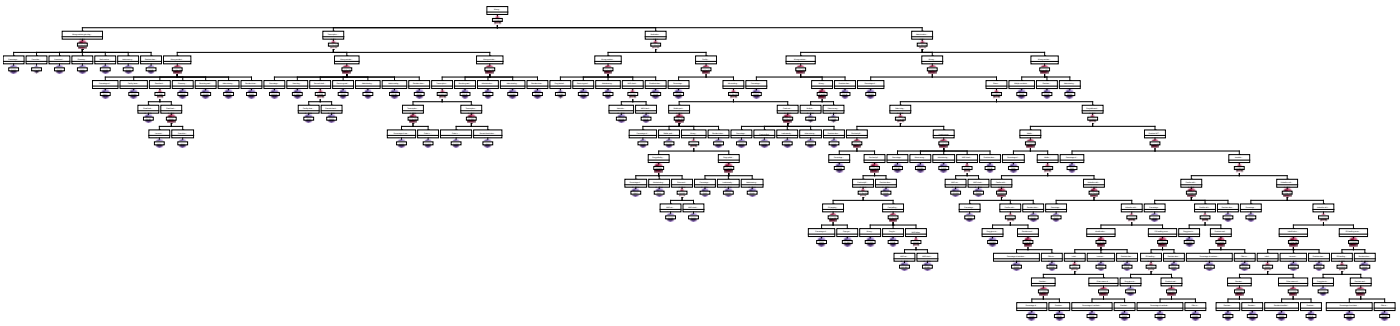


Figure 2 displays the top of the nursing facilities wrong resident tree, which is very similar to the CBC model (not shown). This example illustrates how to "read" or interpret a risk/fault tree. The triangles are transfer gates: meaning that there is more below that specific element in the tree that is not shown. Under each of these high-level overviews is a detailed model of the combinations of failures that will result in a top-level resident event. When interpreting these predictive models, it is important to remember two things. First, the top-level event is not an "adverse drug event" in the sense that it has resulted in harm; rather, the resident did not receive a drug as intended. Second, most errors do not result in harm to patients.[8,10,12]

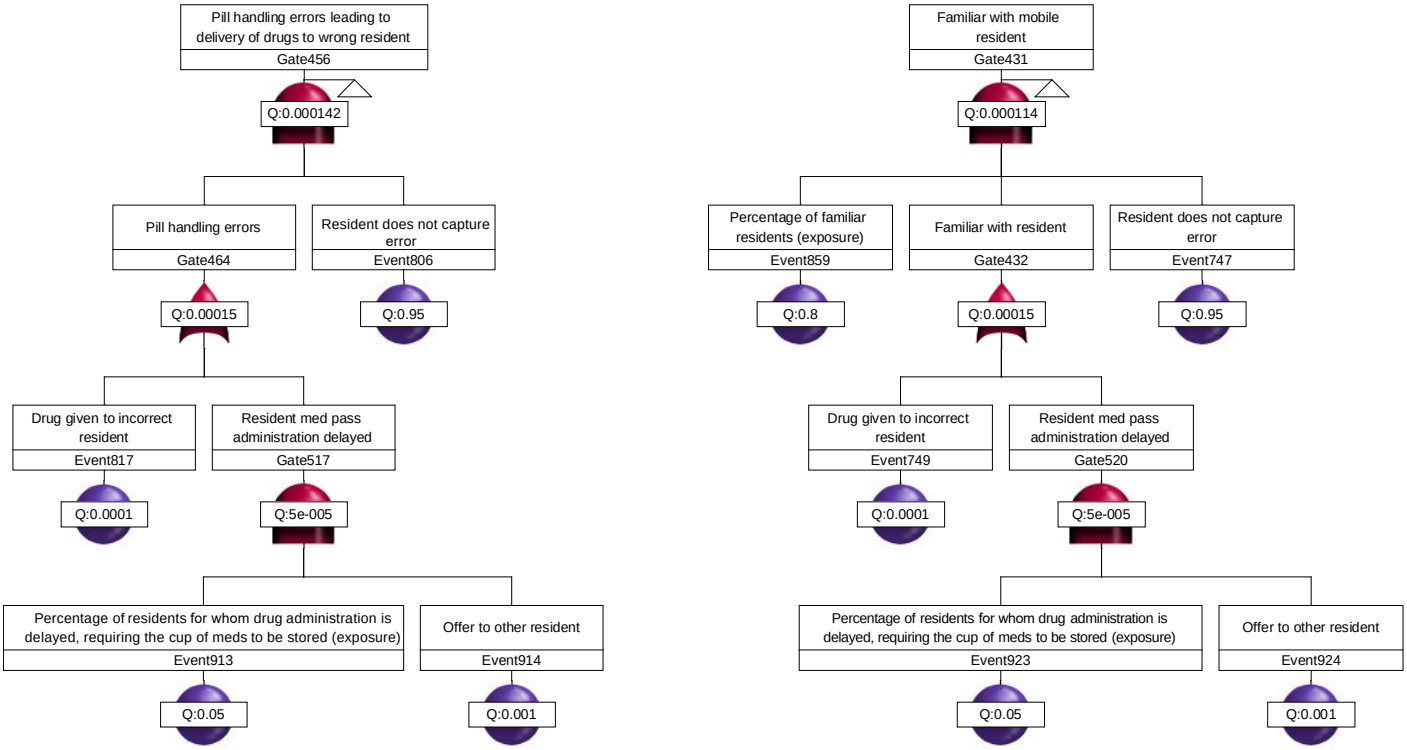
This highest level of the risk tree illustrates that there is a 2.29 per 10,000-dose chance (.000229) of a resident receiving a drug intended for another resident. The causes of this event range from a physician ordering a drug for the wrong resident to the medication aide simply walking up to the wrong resident and giving them someone else's medication cup of pills. The rates below the top-level "OR" gate are the rates associated with the individual major branches on the tree. Figure 3, below, displays the full risk tree for wrong resident.

Figure 3. Wrong Resident Risk Model in Nursing Facilities



The trees have been structured from left to right based on where an error is initiated: in ordering, in transcription, in medication processing (i.e., dispensing and facility storage), and in administration. Looking across the high-level risks, 80% of the risk is within the far-right box (administration-initiated events). Thus, to significantly reduce wrong resident errors, the inquiry should focus on the combinations of failures within the administration path.

Figure 4. Highest Risk – Wrong Resident – Nursing Facility



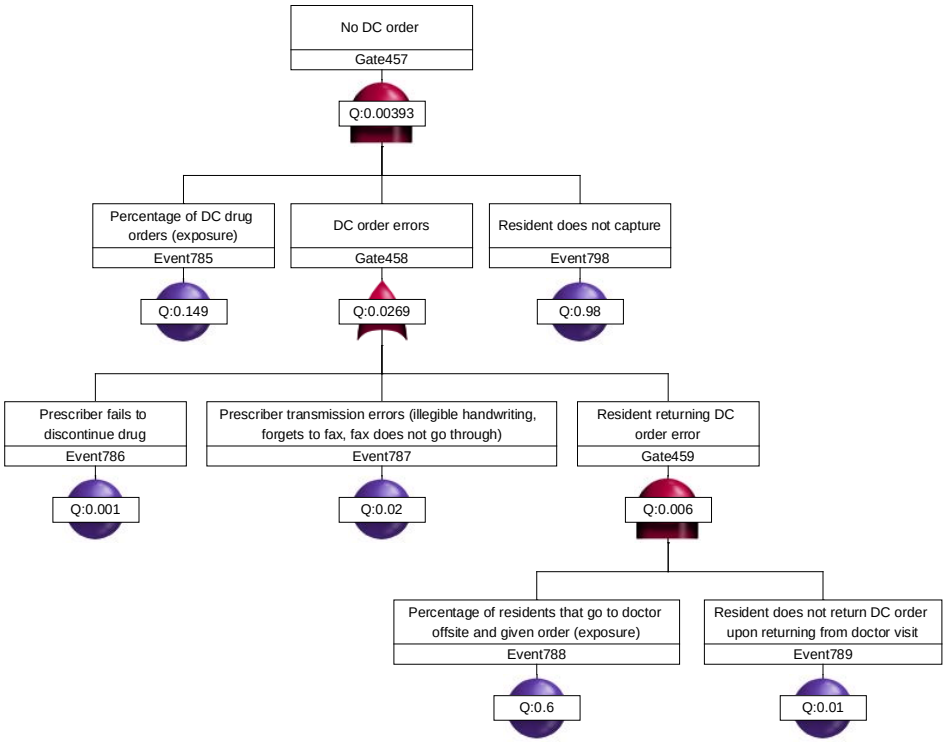
Historically, LTC has not placed as high an emphasis on resident identification as acute care does, because resident turnover is low and most residents are well known by staff. In the survey sample, staff reported knowing 90-95% of their residents well. In long-term care, "patients" are called "residents," and very few "residents" want to wear symbols of living in an institution, like ID armbands. Community-based care is designed as a residential environment, where being treated like a patient is not desired. Faced with this challenge, most facilities include photos of each resident on their MARs to assist staff to identify residents; however, these are not always useful, because "…little, old, gray-haired ladies look a lot alike." This LTC cultural dimension influences the dominant risks identified in the models. The two dominant risk pathways for wrong resident errors in both nursing and community-based care facilities (illustrated for NFs in Figure 4) result from mental slips or lapses,[35] whereby a medication aide or nurse simply picks up the wrong stored med cup or walks up to the wrong familiar resident and delivers the medications. This type of human error typically occurs during routine tasks. When administering meds to an unfamiliar resident, nurses or medication staff will perform an extra step to confirm a resident's identity (often by asking another staff member) that is not performed when the medication aide is familiar with the resident. They have a higher degree of alertness if the resident is unfamiliar, reducing the likelihood of this type of mental slip or lapse.

Wrong Drug: If ever the adage "live by the sword, die by the sword" applied to this risk modeling, it is in the modeling of wrong drug. In these models, (illustrated here in Figure 5) "wrong drug" is characterized as an incorrect medication given to an intended resident at the first dose after the order. As the model developed, the modeling team identified the failure to discontinue (d/c) a medication as one path to the top-level event of "wrong drug." In fact, failure-to-discontinue errors that would technically allow a medication to be delivered for at least one additional dose ended up dominating the wrong drug model. This problem with computer-generated MARs is not new. It was identified by Dean et al. In 1995, in their comparison of a British and an American hospital. It occurs in part because the discontinuation process does not have the controls that one sees in the ordering of a new medication. In the ordering of a new medication, the pharmacist will review the order, the nurse might review the order, and the medication aide will review the order. It is a redundant system that can identify and correct many of the wrong drug errors. In contrast, for failure to discontinue a drug, it merely takes a physician's office to forget to fax the order to the facility, a resident to forget to deliver the order to the facility after an office visit, or a nurse to forget to transcribe the order into the MAR.

Errors due to missed d/c orders in computer-generated MARs are partially driven by a cultural norm shared by prescribers and nurses. Prescribers frequently do not write formal orders to discontinue the original order when a dose is changed on an existing drug (43% NFs and 34% in CBCs) or when changing drugs within a class (e.g., Zantac for Tagamet; 57% NFs and 53% CBCs), because they expect the nurse to intuitively know that the prior order is discontinued (d/c'd). Recording and tracking d/c's is a process full of single failure paths, meaning high risk. This is especially problematic during the monthly MAR change-outs, when many facilities reconcile their new MARs against the original prescriber orders. If no

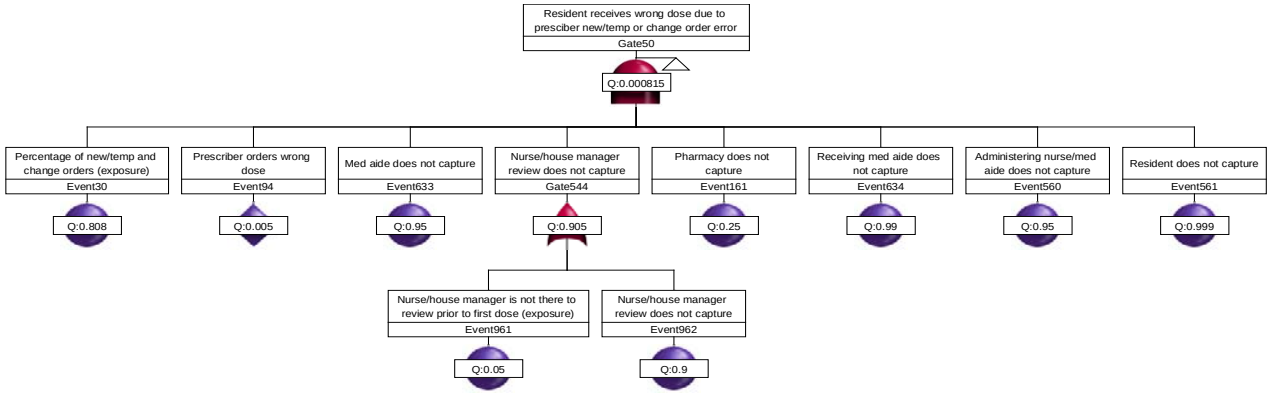
prescriber d/c order is in the chart, in medical records, or transmitted to the pharmacy producing a CBC MAR, the medication continues onto the next month's MAR unless caught when the old (where the nurse probably crossed out the d/c'd drug) and new MARs are cross-checked. Most are caught, but a few get through during the window between the new MAR being checked and the old MAR pulled.

Figure 5. Highest Risk – Wrong Drug – Nursing Facility



Wrong Dose: The models for wrong dose again looked very similar between nursing facilities and community-based care facilities (see Figures 6). For wrong dose, the dominant risk was the initial physician prescribing a clinically inappropriate dose or frequency that simply makes it through the system without being caught. In similar ST-PRA models within the acute care setting conducted by Outcome Engineering (the risk modeling consultants to this project), prescriber error drives wrong dose models. Even with a 1 in 500 rate assigned to initial physician misordering of dose, it is this error that is dominant. One reason for this is that the vast majority (85%) of drugs delivered in our sample of LTC facilities are pills packaged in unit-dose, 30-day blister packs. By exposure alone, blister pack drugs dominated the risk model. Given the dose error controls exerted by blister packs compared with bulk drugs, prescribing errors rise to the top.

Figure 6. Highest Risk – Wrong Dose – Community-Based Care



Beyond that specific risk, both wrong drug and wrong dose models show initial prescribing or ordering mistakes as significant risks. While working on the model, prescribers shared that they often felt frustrated when they received telephone or faxed requests for new or change orders from LTC facilities. Basic patient and clinical information were often missing, the quality of staff assessments of the patient's condition varied from person to person, and they often felt they were "flying blind" when giving orders for a particular resident—especially on nights and weekends when they couldn't access their patient records. When commenting on dosing errors, they noted that each insurer has different

formularies, and each nursing facility has its own combination of emergency drugs on hand. When prescribing, they often don't know whether a particular drug or dose will be available for their patients, and they may be forced to prescribe drugs that they don't know well, making them more prone to dosing errors. Lack of clinical information and decision-making support to prescribers is a weak link in the LTC wrong drug and dose models. Aside from simply ensuring that each change order includes a d/c for the drug or dose being changed, prescriber communication/decision support and reliable means to get this information back to the facility rise to the top of the list of overall risks.

Omissions: The omissions model turned out to be the most complicated model, given the many high likelihood failure paths that can result in medication omission. In the two branches seen in Figures 7 and 8, five different failure paths are shown: preauthorization omissions, resident unavailable, resident refuses med, resident unable to swallow, and resident simply skipped over in the medication pass. What can be seen in the omission model is a large number of varied failure combinations, with no small number of failure combinations that dominate the model. It became clear to the modeling teams that omissions were the least-controlled outcome within the medication administration process, with many single failure paths leading to the top-level outcome.

Figure 7. Highest Risk – Omission – Nursing Facility

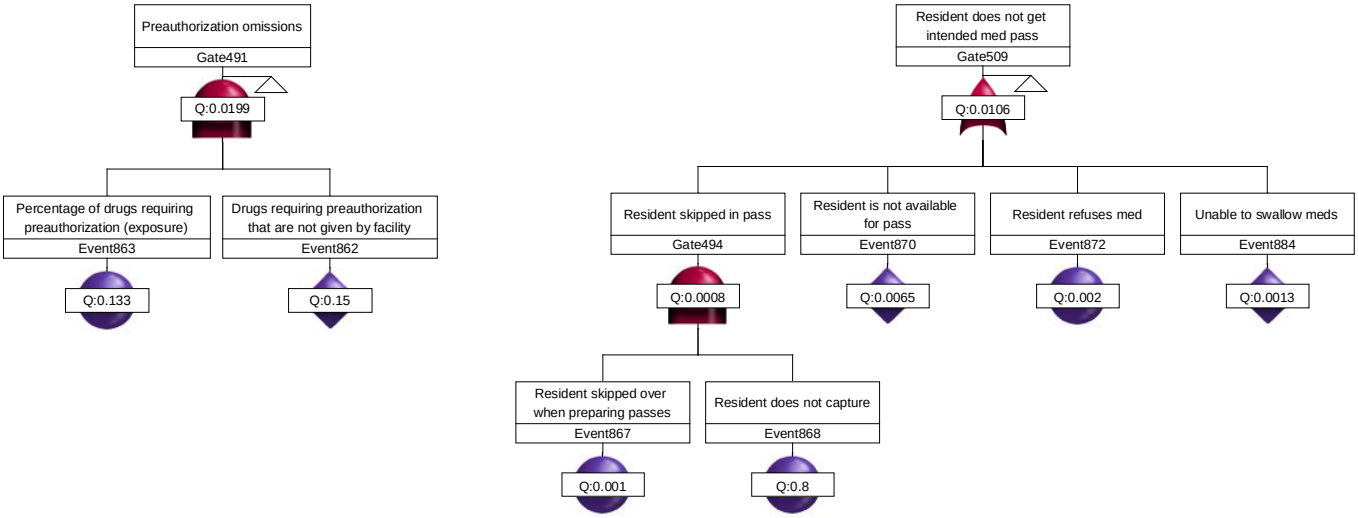
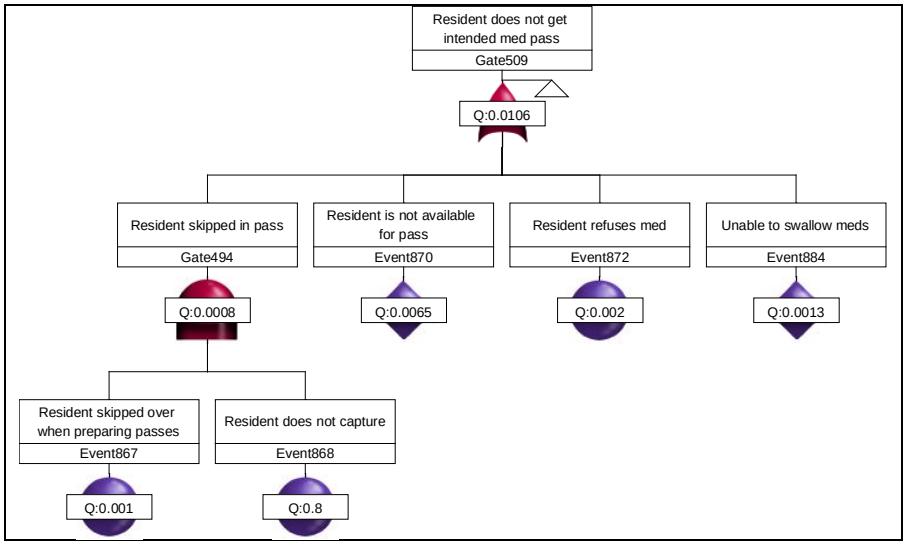


Figure 8. Highest Risk – Omission – Community-Based Care



Validation

Step 1: Comparison of Relative Risks in Models to Selected Drug Error Literature

The top-level event error rate estimates generated by the models are not generally comparable to rates published elsewhere, because published study definitions and conditions vary substantially from those used in the models (see Appendix A). A more useful comparison is the relative risk in the models (highest to lowest) compared with other studies. As noted in an earlier section, the literature generally ranks omissions as the most frequent type of error, followed by

wrong dose, wrong drug, and wrong resident. The Oregon models rank omission as the highest risk and wrong resident as the lowest risk, consistent with other studies; however, the relative risks of wrong dose and drug are reversed in the models compared with findings from other studies. There are at least two potential reasons why the models rank wrong dose risks lower than other published reports.

First, as mentioned earlier, most of the drugs delivered by Oregon facilities are oral solids (tablets, capsules, etc.). In the validation survey, about 85% of the prescription drugs are blister- or bubble-packed on cards. There are very few studies evaluating the merits of this type of unit dosing in LTC facilities[36]; however, unit-dose packaging is an active control for wrong dose errors. What appears to be under-reporting of wrong dose administration errors may be a reflection of the impact of the prevalence of unit-dose bubble/blister packaging of oral drugs. Second, the relative frequencies of administration errors and prescribing errors may be underestimated in the wrong dose models. Data collected in the validation survey suggests that one denominator used to calculate administration event rates may be too high. One of the denominators in the models assumed 45 residents/med pass. The validation sample med pass means were 35.9 (NF) and 30.4 (CBC) residents. This might explain some of the differences observed but is probably not the most important source of bias in the models.

Our experience also suggests that healthcare personnel in the modeling teams may not be able to detect or estimate the frequency for some types of errors they and their coworkers are making, which is not a new finding.[16,37,38,39] Prescribers review each other's work in hospitals and do see each other's errors, but the individual primary care practitioner may or may not be able to accurately estimate his or her own prescribing errors. During medication administration, many single failure path errors occur that the nurse, aide, or caregiver cannot detect, and it is unlikely they can accurately estimate the frequency of these errors. If comparable error rate data are available from published studies, they can be used to stimulate discussion and "anchor" rate estimates for types of errors unlikely to be detected by practitioners or facility staff. When the models are revised, the tables in Appendix A will be used to stimulate discussion about improving estimates for difficult-to-detect events. It is important to note that, although the absolute rates are low, prescriber ordering wrong dose is the highest relative risk in the model, which is a finding consistent with published sources.

Step 2: Survey Results: Variation between Models and Statewide Sample

Probabilistic risk assessment models should be complete and accurate reflections of the processes they are describing, although the probabilities associated with particular events can vary substantially depending on the analyst.[27,28] The validation survey captured data on a large number of LTC medication delivery system policies, processes, practices, and rates. During the survey, only one new process variation was identified from survey interviews. In both NFs and CBCs, about half the nurses and caregivers (46.5% NF; 50.6% CBC) who take telephone orders jot them down on scrap paper before transcribing them onto order forms. Most of the time, staff do this because they want to check their spelling before transferring the information to the chart and MAR. This practice adds a second level of transcription error risk not reflected in the current models. Studies have identified duplicate transcription as a risk factor.[40] Finding just one important process variation that isn't in the initial models suggests that these models have accurately captured the major process variations in Oregon NFs, ALFs, and RCFs with 20 or more beds.

Exposure, error, and at-risk behavior rates are the foundations for risk estimates. If the models are to be used for statewide planning and improvement tools, they should reasonably represent the important risks found in the statewide facility sample. Two members of the research team (DM and MH) reviewed and compared 101 rates derived from the models with rates reported in the validation survey, and they then estimated whether any of the differences between rates would substantially alter the models. Of the 101 comparisons, 11, or 10.9%, were different enough to change the top-level risk in the NF and CBC omissions models. All but one involved five failure path errors common to both the NF and CBC models:

- Resident refusal to take medications
- Resident refusal of an injection
- Resident unavailable to take the medication
- Resident unable to swallow the medication
- Liquid not being administered

Pending review of the survey results by the modeling teams to give them time to investigate and discuss the survey findings, the statewide omissions models will not be changed. As noted, a few validation rate estimates are substantially higher than the model; however, they do not change the relative rankings of the top-level risks. The validation survey data largely confirms that the models are accurate and complete; however, the variations identified deserve further investigation and possible inclusion in later generations of these models.

Lessons Learned

First, ST-PRA modeling of medication risks at state level is possible and practical, with some caveats:

1. It is resource intensive and needs experienced and communicative people in modeling groups.
2. The processes being modeled should be fairly consistent from facility to facility (e.g., driven by culture, practice standards, and/or regulatory requirements).
3. The modeling process requires very skilled facilitation to keep the size of the trees manageable and still robust enough to capture the important processes leading to top-level events.
4. The fault tree software is sophisticated and requires skill to input data.
5. It is important to have clear and logical boundaries to keep models a manageable size.
6. Sustained support of major stakeholders is important, particularly from LTC providers and regulatory agencies.
7. It was helpful that the study was organized by a "neutral" party, the state public health function, and carried out by independent researchers with no "agenda" other than producing credible risk models.

The Modeling and Validation Interview Processes

1. The error definitions evolved over time as new process variants were described in the modeling groups. The processes, not the literature, drive the definitions. You may not have definitions that fit other studies, but they have to reflect operational realities.
2. Defining and collecting data for rate denominators should be done very early; extra care needs to be taken in ensuring that the assumptions behind the rates aren't skewed, so basic information from a larger sample of facilities may be necessary to determine key elements. It's important to keep good records of the denominators and how they are calculated for future reference.
3. In doing statewide models, there will be many inconsequential variations and a few variations that make an important difference in the top-level event. The research team needs to debate and consider carefully which variations need risk modeling and use their modeling teams as sounding boards.
4. The modeling teams needed basic process maps to begin their work and benefited from seeing the entire model as it was built but normally worked on one branch at a time. Two notetakers recorded the modeling group's input during each session, but the actual model building using the Relex[41] software was normally done immediately after the group met. The modeling team reviewed the updated model at the next meeting, before starting on the next section.
5. Two to three weeks elapsed between the modeling sessions, because facilities could not spare medication staff for more than one half-day every other week or so. The teams would have been more efficient if a larger block of time and fewer meetings were scheduled for each of the chains.
6. Logistics for running seven modeling groups were challenging. Scheduling meetings and maintaining communications with facility staff continued to be problematic. We should have sent meeting schedules directly to them, with copies to the facility managers so that everyone was "in the loop."
7. Had there been sufficient time, it would have been better to complete the NF model and then the CBC, because simultaneously keeping the rates and models separate was a "bookkeeping" challenge.
8. Care must be taken to avoid facial, verbal, or body language cues that might be interpreted as being critical of comments from modelers. Although team members need to be able to debate and discuss practices that impact risk, there should be no "cops" in the room, and that may mean that some people won't be appropriate choices either as team members or as research staff.
9. Survey interviews were generally not successful at collecting information on at-risk behaviors. Respondents are not familiar with the modeling process and haven't built up sufficient rapport with research staff to talk about deviations from standard policies. They are comfortable talking about themselves or coworkers "forgetting" to process an order, but they are much less likely to describe things like one shift or person routinely leaving several orders for the next shift to process or when and how medications are "borrowed"—things the modeling groups were comfortable discussing in relation to risks of errors. A secret ballot was used in some modeling groups and during the survey interviews to collect information on the percent of time staff don't review the MARs for each medication given to a resident, a practice facilitated if drugs are organized and ordered by time, with one bubble/blister pack card for each med pass—reducing dependence on the MAR and increasing the risk of wrong drug and dose errors. The secret ballot worked well for gathering information on this single question and might be useful to gather data on additional at-risk behaviors in future survey interviews.

Building and Implementing Risk Reduction Strategies

To build intervention strategies, the State of Oregon and Oregon Health Care Association sponsored a workshop that included LTC facility domain experts (nurses, CMAs, caregivers) who built the model and additional stakeholders who were seeing the model for the first time. They reviewed the top-level risks for each model and brainstormed interventions.

In the next stage of the process, the strategies were compiled with additional information for each strategy, including prevalence of the target element, strategy effectiveness, degree of stakeholder influence, whether the strategy might affect multiple top-level events, predicted impact on top-level event from the model, legal or regulatory issues, and estimated time needed to implement. The team evaluated the items to identify the "low-hanging fruit" that could be implemented within a reasonable amount of time. There are often several competing strategies to address the same risks, so each had to be evaluated separately.

Managers from the State of Oregon and the Oregon Healthcare Association reviewed the tables and used the following criteria to establish their final priorities:

- The percentage of top-level risk that is addressed by the intervention to estimate potential "impact" or effectiveness at reducing risk
- An estimate of the changeability in terms of cost
- An estimate of the cultural ease in implementation (i.e., would the culture support the change)
- Given limited resources for effectively implementing large-scale changes, selecting only one or two strategies to implement in 2005

Based upon this assessment, four risk reduction strategies were identified. The top two are slated for implementation in 2005.

1. Improving communication tool(s) for facilities to use when requesting new or changes to existing orders from prescribers; for example, forms for faxes, for T.O.s, and to give to residents going out to the provider's office. The forms could include a prompt for d/c orders (potential to reduce risks of wrong drug up to 64.8%) and ensure that prescriber (and ultimately the pharmacy) has necessary patient (age, sex, wt, ht, diagnoses, allergies) and clinical (renal, liver function, or other recent lab test results and monitoring data like blood pressures, CBGs, etc.) information when providing medication orders by phone or fax. The estimated impact is potential to reduce risks 0.4% or more for wrong drug prescribed and 62.7% for wrong dose by providing prescriber who needed information and by enhancing the pharmacy's ability to detect wrong dose/drug prescribing errors.
2. Verify resident ID with two independent sources (estimated impact: could reduce up to 42.9% of risk in model). The dominant risk in the wrong resident model is for the mobile, known resident. When questioned, modeling team members and the majority of survey respondents agreed that this represents the highest-severity event for their residents, because the resident is likely to receive a whole pill cup of medications, not a single drug. The typical LTC resident does not wear plastic identification bracelets because of personal preference or concern about skin tears from the devices (must be reported as potential evidence of abuse!) and because over 90% of them are well known by the staff.

DISCUSSION AND CONCLUSIONS

The ST-PRA modeling process is a unique tool; it gives us a picture of how robust the system is, estimates how often individual errors occur and how they contribute to top-level risk, and explores how frail the system is in other areas. In this case, the Oregon Long-Term Care Risk Models represent the impressions, data, and best risk estimates of medication aides, nurses, pharmacists, and physicians who work in long-term care. The models are imprecise (because they are models) and no doubt inaccurate in some areas, for reasons noted in earlier sections of this report. Survey data largely confirm the models' representation of NF, ALF, and RCF medication delivery processes; however, there are some branches or models that probably need review and potentially revision. Relative risks of wrong drug, dose, resident, and omission are consistent with published studies, with the exception of wrong dose. It is not entirely clear whether wrong dose errors are substantially less frequent in LTC, as the Oregon models suggest, or if methodological issues identified account for the observed differences.

The models, nevertheless, are the first statewide model of medication risk and provide deep insights into the LTC medication delivery process not available elsewhere. Risk models are vehicles for a shared understanding of the failure paths leading to resident harm. It is the first step in facilitating shared goals and agreement between stakeholders about risks and priorities—from the Oregon Health Care Association to the State of Oregon, from individual facilities to their supplier pharmacies—because it objectively describes the processes, behaviors, and equipment that lead to system failures. With these risk models in hand, the stakeholders in Oregon have used the model to identify risk reduction strategies that will have great impact across Oregon's LTC medication delivery system.

As shown in the results, at a high level, the model shows a remarkable amount of robustness within the medication delivery system in Oregon's long-term care facilities. In the best of circumstances, probability assessment models are subject to missing failure paths, mischaracterized dependencies between errors, and misestimated failure rates, and they are driven by the need to maintain the model(s) at a manageable size, creating the potential for leaving out process and procedural variations that may lead to risk.[27,28,42]

Notwithstanding limitations of the probabilistic risk assessment methodology, ST-PRA offers four advantages over current risk management methodologies:

1. ST-PRA provides a structure and process that allows gathering sometimes highly charged information about policy, procedure, and/or behavioral deviations not otherwise available.

2. The models provide contextual maps of the errors and behaviors leading to system failures so that policymakers, regulators, and managers can identify, prioritize, and prospectively model risk reduction interventions using ST-PRA.
3. Models are dynamic; they are designed to evolve as fresh data from new studies, patient safety reporting systems, or facility incident reporting systems are used to refine probability estimates for different elements in the models.[3]
4. Policymakers and regulators are able to appreciate the unanticipated consequences of particular enforcement actions (i.e., increased borrowing behavior to avoid citations for "drug not available" or the time pressures introduced by interpretations of the federal "2-hour rule"[18] governing the time a drug is administered to a patient).

This research complements earlier studies of medication errors conducted by researchers over the past 20+ years. It creates a rich contextual map that offers provocative insights into the deep systems and human factors issues that govern medication error risks. Understanding errors from a systems perspective helps managers and policymakers avoid over-reacting to single and often infrequent but sometimes well-publicized adverse events. These models define risks objectively and in sufficient detail that specific problem areas can be identified—allowing state agencies and providers to develop agreements about acceptable and unacceptable risks and their different roles in addressing the risks.

The identification of previously unappreciated single fault failures is heightening awareness of medication ordering and administration practices in Oregon. At least one large local geriatrics practice has started writing d/c orders when changing medication orders. Having a visible model of risk facilitates trust, communication, and concerted actions to reduce risk if everyone "owns" the same model. Diverse stakeholders in sometimes adversarial or competitive relationships are able to collaborate to promote safety. Regulators are also interested in using the model to address unintended consequences of regulatory practices and to shift resources/policies to reduce the frequent and clinically important risks. Citing facilities for low-risk procedural deviations is not in the public's interests, but, until the models were completed, providers, policymakers, and regulators could not visualize or appreciate the contributions of many systems risks identified in the models. After seeing these different failure paths and the probabilities assigned by the domain experts, Oregon's LTC community has been working together to prioritize which risks deserve their immediate attention.

Future Directions

Many complex processes are linked across the continuum of care (e.g., medications prescribed and administered to patients who are transferred from home to acute or LTC). Risk modeling of these "crossover" processes has the potential for reducing risks and improving care coordination, integrated care, and person-centered disease management models of service delivery. Given that these are "first-generation" models, they represent a foundation for additional work, a place to start. Sustaining the models, extending them to new applications, refining probabilities and rates with new data, and institutionalizing the modeling program into some type of organizational structure that can fully utilize this prospective QI/patient safety tool are continuing challenges to be met; however, the models are already changing the face of risk management in Oregon.

List of Publications and Products

Comden SC, Marx D, Carley, MM, Hale M. Using Probabilistic Risk Assessment to Model Medication System Failures in Long-Term Care Facilities. *Agency for Healthcare Research and Quality; Advances in Patient Safety; From Research to Implementation.* Rockville, MD: 2004 (in press)

Carley MM, Comden SC, Hale M. Risk Models to Improve Long-term Care Medication Safety in Oregon. *Making the Health Care System Safer, Third Annual Patient Safety Research Conference;* 2004 Sept 26-28; Arlington, VA. Agency for Healthcare Research and Quality. http://www.ahrq-psrcc.org/AnnualMeeting2004/2004_Presentations/AHRQ_Web/sessions/VI-C.pdf.

List of References

[1] Institute of Medicine. *Improving the Quality of Long Term Care.* Washington, DC:National Academy Press; 2001.
[2] National Center for Assisted Living. *Facts and Trends 2001: The Assisted Living Sourcebook*. Washington, DC: American Health Care Association; 2002:xii-42.
[3] Administration on Aging. *A Profile of Older Americans: 2002*. Washington(DC): 2003.
[4] Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients; population based review of medical records. BMJ 2000;320(7237):741-4.
[5] Field TS, Gurwitz JH, Avorn J, et al. Risk factors for adverse drug events among nursing home residents. *Arch Intern Med. 2001:161(13):l629-34.*
[6] Gurwitz JH, Field TS, Avorn J, et al. Incidence and preventability of adverse drug events in nursing homes. *Am J Med. 2000:109(2):87-94.*

[7] Monet J, Gurwitz JH, Avorn J. Epidemiology of adverse drug events in the nursing home setting. *Drugs Aging*. 1995:7(3):203-11.

[8] Bates DW, Boyle DL, Vander Vliet, et al. Relationship between medication errors and adverse drug events. *J Gen Intern Med.* 1995:10(4):199-205.

[9] Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. *Arch Intern Med.* 2002;162:1897-903.

[10] Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA.*1997:277(4):312-7.

[11] Bobb A, Gleason K, Husch M et al. The epidemiology of prescribing errors: the potential impact of computerized prescriber order entry. *Arch Intern Med.* 2004;164(7):785-92.

[12] Flynn EA, Barker KN, Carnahan BJ. National observational study of prescription dispensing accuracy and safety in 50 pharmacies. *Am Pharm Assoc (Wash).* 2003;43(2):191-200.

[13] Dean BS, Allan EL, Barber ND, Barker KN. Comparison of medication errors in an American and a British hospital. *Am J Health Syst Pharm. 1995;52(22):2543-9.*

[14] Cohen, MF. *Medication Errors*. American Pharmaceutical Assoc. Washington (DC);1999.

[15] West DW, Levine S, Magram G, et al. Pediatric medication order error rates related to the mode of order transmission. *Arch Pediatr Adolesc Med.* 1994;148(12):1322-6.

[16]Leape L, Bates DW, Cullen DJ, Cooper J, Demarco HJ. Systems analysis of adverse drug events. *JAMA.* 1995;274:35-43.

[17] Seniors and People with Disabilities. Top ten survey citations 1/2002-12/2002 for long term care and community based care facilities, compiled by Dept. of Human Services. Portland,OR: 2003.

[18] Hale M, Slonim A, Allen B, et al. Socio-technical probabilistic risk assessment: its application to patient safety. In International Conference on Probabilistic Safety Assessment and Management, 14-18 June. Berlin, Germany: Springer-Verlag; 2004.

[19] Pate-Cornel, E. Medical applications of engineering risk analysis and anesthesia patient risk illustration. *Am J Ther*. 1999:6(5):245-55.

[20] Marx D, Slonim A. Assessing Patient Safety Risk Before the Injury Occurs: An Introduction to Socio-Technical Probabilistic Risk Assessment in Healthcare. *J Qual Safety Health Care.* 2003:12 (Suppl II):ii33-ii38.

[21] Wreathall J, Memeth C. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. *J Qual Saf Health Care.* 2004:13:206-212.

[22] Battles JB, Kanki BG. The use of socio-technical probabilistic risk assessment at AHRQ and NASA. In International Conference on Probabilistic Safety Assessment and Management, 14-18 June. Berlin, Germany: Springer-Verlag; 2004.

[23] Seniors and People with Disabilities: November, 2004 licensure list. Dept. of Human Services. Portland,OR.

[24] American Health Care Association: *2002 CMS OSCAR Data Reports*. Washington, DC; 2003.

[25] National Center for Assisted Living. *Facts and Trends 2001: The Assisted Living Sourcebook*. Washington, DC: American Health Care Association; 2002:1-2.

[26] Agency for Healthcare Research and Quality. *Advances in Patient Safety; From Research to Implementation.* Rockville, MD: 2004 (in press).

[27] Linnerooth-Bayer J, Wahlstrom B. Applications of probabilistic risk assessment: The selection of appropriate tools. *Risk Analysis*. 1991;11:239-248.

[28] Macwan A, Mosleh A. A methodology for modeling operator error in probabilistic risk assessment. *Reliability Eng and Syst Safety.* 1994;45: 139-157.

[29] Advisory Committee on Reactor Safeguards. Subject: NUREG-1624, Revision 1, Technical Basis and Implementation Guidelines for a Technique for Human Event Analysis (ATHEANA). NRC Letters and Reports: 12/15/1999.

[30] Kanki BG, Marx D, Hale MJ. Socio-Technical Probabilistic Risk Assessment: Its Capabilities and Limitations. In International Conference on Probabilistic Safety Assessment and Management, 14-18 June. Berlin, Germany: Springer-Verlag; 2004.

[31] Lau DT, Kasper JD, Potter DE, Lyes A. Potentially inappropriate medication prescriptions among elderly nursing home residents: their scope and associated resident and facility characteristics. *Health Serv Res.* 2004(39(5):1257-76.

[32] Sloane PD, Zimmerman S, Brown LC, et al. Inappropriate medication prescribing in residential care/assisted living facilities. *J Am Geriatr Soc.* 2002;50(6):1001-11.

[33] Oregon Health Care Association, *Licensed Facilities, 4/2004*. Wilsonville, OR: 2004

[34] Broockvar K, Fishman E, Kyriacou CK, et al. Adverse events due to discontinuations in drug use and dose changes in patients transferred between acute and long-term care facilities. *Arch Intern Med.* 2004;164:545-550.

[35] Reason, J. *Human Error.* Cambridge, UK; Cambridge University Press, 1990.

[36] Reitberg DP, Miller RJ, Bennes JF. Evaluation of two concurrent drug-delivery systems in a skilled nursing facility. *Am J Hosp Pharm*. 1982;39:1316-20.

[37] Barker KN, McConnell WE. The problems of detecting medication errors in hospitals. *Am J Hosp Pharm.* 1962;19:360-69.

[38] Barker KN and Allan EL. Research on drug-use-system errors. *Am J Health-Syst Pharm.* 1995;52:400-403.

[39] Perlstein PH, Callison C, White M, et al. Errors in drug computations during newborn intensive care. *Am J Dis Child.* 1979;133:376-379.

[40] Pichon R, Zelger GL, Wacker P, et al. Analysis and quantification of prescribing and transcription errors in a paediatric oncology services. *Pharm World Sci.* 2002;24(1):12-5.

[41] Relex software, version 7.6. Greensburg, PA; Relex Software Corporation; 2003.

[42] Martz HF, Picard, RR. On comparing PRA results with operating experience. *Reliab Eng and Syst Safety.* 1998;59:187-199.

Appendix A. Table 1. Summary of Potential for Harm by Stage and Medication Error Category

Error Category	**Prescribing**			**Dispensing**	**Administration**
	Lesar et al. (1990) % of All Errors with Potential for Significant Harm	Lesar, Briceland, Stein (1997) % of All Errors with with Potential Adverse Effects	Lesar, Lomaestro, Pohl (1997) % of All Errors with Potential Adverse Effects	Flynn, Barker, Carnahan (2003) Key Finding: Over 50% errors not detected by the pharmacy Frequency by Error Type	Barker, Flynn, et al. (2002) Key Finding: 19% of all doses were in error; no difference in rates between NFs and acute care hospitals % Clinically Significant Within Error Category
Wrong drug	7.3	5.0	4.1	6/4,481 or .001	
Known allergy	11.7	12.9	14.4		
Duplicate therapy	5.7	5.0	6.1		
Unauthorized drug					14
Wrong Dose					
Overdose	38.9	41.8	37		11
Underdose	25.5	16.5	19.1		
Wrong form	3.6	11.6	11.2	1/4481 or .0002	33
Wrong dose					15
Wrong strength				8/4481 or .002	
Wrong quantity				9/4481 or .002	
Wrong Patient	1.9	0.4	0.9		
Omission					
Dose	na	na	na	2/4481 or .0004	6

Appendix A. Table 2. Medication Error Frequency by Stage and Medication Error Category

Category	Prescribing/Ordering		Dispensing	Administration
	Lesar, Briceland, Stein (1997) Case study: 631-bed tertiary teaching hospital; 178,000 orders handwritten or on preprinted forms processed with 2103 clinically or significant pharmacist detected errors. Researchers investigated every third error (696) to determine proximal causes. Rates below were calculated from published study data. **Key findings:** Dominant factors associated with error were inadequate drug knowledge (present in 30% of errors) and patient information (e.g., history, advanced age, renal function, weight, allergies)—present in 29.2% of errors. Calculation and expression of rate errors were found in 17.5% of errors; 13.4%of errors involved incorrect drug names dosage forms or abbreviations, and 3.2% involved wrong dosage form. Most common drug classes involved in errors were antimicrobials and cardiovascular drugs.	Bobb, Gleason, et al. (2004) Case study: 700-bed teaching hospital. Pharmacist detected 1111 prescribing errors. Orders handwritten or on preprinted forms. **Key findings**: Most errors occurred at admission. Of errors identified, 31% were clinically significant and most often associated with anti-infective agents, incorrect dose, and deficient medication knowledge. Most would require monitoring but 11.5% or 7.2/1000 would have been harmful to patient.	Flynn, Barker, Carnahan (2003) Sample: 4481 observations in national sample of 50 chain, independent, and health system pharmacies **Key Findings:** Dispensing accuracy ranged from 87.2-100% or about 17 errors/1000 orders filled. Over 50% of errors not detected by the pharmacy. Chances of getting a prescription incorrectly filled is 1/30. About 6.5% or 1/1000 orders filled contain clinically significant errors.	Barker, Flynn, et al. (2002) Sample: 3216 observations at 18 NFs and 18 acute hospitals in two states **Key Findings**: 19% of medications administered contained errors; no difference in rates between NFs and acute care hospitals. About 7% were clinically significant.
	Rate of Clinically Significant Errors Detected by Pharmacists /1000 Orders	**Rate of Clinically Significant Errors Detected by Pharmacists /1000 Orders**	**Rate of Dispensing Errors per 1000 Orders**	**Rate of Errors per 1000 Doses**
Wrong drug	0.6	1.2	1.3	
Known allergy	1.5	0.9		
Duplicate therapy	0.6	0.7		
Unauthorized drug				6.8
Drug/drug interaction		0.4		
Total	2.7	3.2	1.3	6.8
Wrong Dose				
Overdose	4.8			
Underdose	1.9			
Wrong form	.3	1.8	0.2	6.2
Wrong dose		7.5[42]		32.0[42]
Wrong strength			1.8	
Wrong quantity			2.0	
Total	7.0	9.3	2.0	38.2
Wrong Patient	0.5		0.02	
Omission				
Omitted drug		0.9		
Omitted dose			0.4[42]	56.9
Wrong time				80.5