

The Clinical Pharmacists' Role in Patient Safety

David J. Warner, Pharm.D.

Director, Center on Practice Development

Senior Consultant, ASHP Consulting



Objectives

1. Describe how clinical pharmacists can influence the safe use of medications for patients.
2. Describe how clinical pharmacists can influence the safe use of medications using automation and information technology.
3. Describe how clinical pharmacists can influence patient safety initiatives at the hospital/organizational level.

American Society of Health System Pharmacists

- Founded 1942
- 43,000-member professional association
- Represent hospital, ambulatory and health-system pharmacists, residents, and students
- ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time.
- The mission of pharmacists is to help people achieve optimal health outcomes.



Clinical Pharmacist Patient Care Services that Improve Safe and Effective Use of Medications



18 Infusion Pump Channels on One Patient With NO EMR Integration



Infusion Therapy is a Complex “Process”



The Roles of the Clinical Pharmacist

- Competent clinician
- Excellent communicator
- Knowledge manager
- Educator
- Leader
- Problem-solver
- Project manager and multi-tasker
- Learner
- Innovator

Where is medication safety?



Basel Statements on the Future of Hospital Pharmacy

- 75 Consensus statements were developed at Global Conference on the Future of Hospital Pharmacy as a part of the FIP 68th Congress
- Developed statements on the following:
 - Overarching statements
 - Medicines procurement
 - Influences on prescribing
 - Preparation and delivery of medicines
 - Administration of medicines
 - Monitoring of medicines
 - Human resources and training

Basel Statements on the Future of Hospital Pharmacy

Select Overarching statements

- The overarching goal of hospital pharmacists is to **optimize patient outcomes** through the judicious, safe, efficacious, appropriate and cost effective use of medicines.
- Hospital pharmacists should serve as a **resource regarding all aspects of medicines use** and **be accessible as a point of contact for health care providers**.
- **All prescriptions should be reviewed, interpreted, and validated** by a hospital pharmacist prior to the medicine being dispensed and administered.

Basel Statements on the Future of Hospital Pharmacy

Select Overarching statements

- Hospital pharmacists **should monitor patients taking medicines** (daily or whenever medicines are changed) to assure patient safety, appropriate medicine use and optimal outcomes. When resource limitations do not permit pharmacist monitoring of all patients taking medicines, patient selection criteria should be established to guide pharmacist monitoring.
- Hospital pharmacists should **ensure that all patients are educated** on the appropriate use of their medicines.

Basel Statements on the Future of Hospital Pharmacy

Select Overarching statements

- Hospital pharmacists should **provide orientation and education** to nurses, physicians, and other hospital staff regarding best practices for medicines use.
- Hospital pharmacists should actively **engage in research into new methods and systems to improve the use of medicines.**

Basel Statements on the Future of Hospital Pharmacy

Select Influences on **prescribing** statements

- Hospital pharmacists should be involved in all patient care areas to **prospectively influence collaborative therapeutic decision-making**.
- Hospital pharmacists should be an **integral part of all patient rounds to assist with therapeutic decision-making and advise on clinical pharmacy and patient safety issues**.
- Hospital pharmacists should **provide continuity of care** by transferring patient medicines information as patients move between sectors of care.

Basel Statements on the Future of Hospital Pharmacy

Select **Preparation and delivery** of medicines statements

- Hospital pharmacists should **ensure that proper storage conditions are provided** for all medicines used in the hospital.

Select Administration of medicines statements

- Hospital pharmacists should **ensure that the information resources needed for safe medicines preparation and administration are accessible at the point of care.**
- Hospital pharmacists should **ensure that allergies are accurately recorded** in a standard location in patient records and evaluated prior to medicines administration.

Basel Statements on the Future of Hospital Pharmacy

Select **Administration of medicines** statements

- Storage of concentrated electrolyte products and other high-risk medicines on patient wards should be eliminated by dispensing ready-to-administer dilutions, or, if necessary, storing such products distinctly labelled in separate or secure areas.
- Hospital pharmacists should be responsible for determining which medicines are included in ward stock and for standardizing the storage and handling of ward medicines.

Basel Statements on the Future of Hospital Pharmacy

- In 2014, hospital pharmacists met again in Bangkok, Thailand to discuss the future of hospital pharmacy practice.
- 65 consensus statements were released in 2015.
- Developed statements on the following:
 - Overarching and governance statements
 - Medicines procurement
 - Influences on prescribing
 - Preparation and delivery of medicines
 - Administration of medicines
 - Monitoring of medicines use
 - Human resources, training, and development

Basel Statements on the Future of Hospital Pharmacy

Select Overarching and Governance statements

- The overarching goal of hospital pharmacists is to **optimize patient outcomes** through the collaborative, inter-professional, responsible use of medicines and medical devices.
- The responsible use of medicines means:
 - That a medicine is only used when necessary and that the choice of medicine is appropriate based on what is proven by scientific and/or clinical evidence to be most effective and least likely to cause harm. This choice also considers patient preferences and makes the best use of limited healthcare resources.

Basel Statements on the Future of Hospital Pharmacy

Select **Preparation and delivery** statements

- Hospital pharmacists should **assume responsibility for storage, preparation, dispensing, and distribution of all medicines**, including investigational medicines.
- Hospital pharmacists should **assume responsibility for the appropriate labeling and control of medicines stored throughout the facility.**
- The **preparation of hazardous medicines including cytotoxics** should be under the responsibility of the hospital pharmacist and prepared under environmental conditions that minimize the risk of contaminating the product and environment, as well as minimizing the exposure of hospital personnel to harm using accepted practice standards.

Exploring Pharmacists' Role in a Changing Healthcare Environment

- Funding for research by several U.S. professional organizations
- White paper published in 2014 focused on understanding the types of services that pharmacists can provide and how the demand for services may change in the future.
- Current practices described:
 - Medication management
 - Medication reconciliation
 - Preventative Services (screenings and immunization)
 - Education and behavioral counseling
 - Collaborative drug therapy management



Exploring Pharmacists' Role in a Changing Healthcare Environment

Medication Reconciliation

- Nearly 70% of patient care transitions result in medication discrepancies, with 1/3 being serious enough to lead to ADEs.
- Quality measures have been related to unplanned readmissions for heart attack, heart failure, pneumonia, and for total hip and knee replacements.
- Data suggests that physicians and pharmacists performing medication reconciliation can produce similar results, but time may limit the physician to perform the service reliably.

Exploring Pharmacists' Role in a Changing Healthcare Environment

Medication Education and Behavioral Counseling

- Counseling linked to better medication adherence as well as better clinical measures for HgA1C, blood pressure, lipids and asthma control.
- Positive impact without explicit collaboration with other HCP
- Positive impacts in smoking cessation and weight management program

What the patient care team looks like today

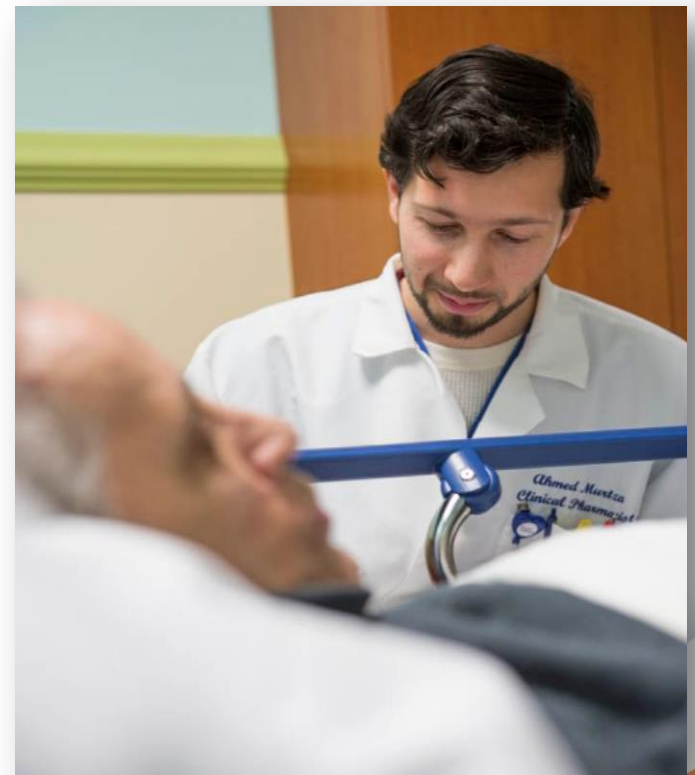
Numerous factors affect the look of the Patient Care Team today

- Schedules of attending physicians
- Schedules of house staff
- Integration of extenders: nurse practitioners and physician assistants
- Use of hospitalist model(s) in many organizations
- The “parade” vs. the smaller (two-person) team
- The type of and effectiveness of the medication distribution system
- The type of and the effectiveness of the electronic health record
- The pharmacist is many times the most consistent member of the team
- The care team pharmacist is many times on more than one team...
(interacting with teams that manage antimicrobials, nutrition, PK, pain, coagulation disorders, medication safety and policy, medication stewardship, and more...)



Patient care areas where clinical pharmacist assignments are most common

1. Critical care units
2. Inpatient medical-surgical units
3. Oncology units
4. Cardiology units
5. Pediatric units
6. Anticoagulation service
7. Neonatal unit
8. Emergency Department
9. Infectious disease service



The Role of the Clinical Pharmacist

- Select and provide the services that are most valuable to your patients, colleagues, and your organization(s)
- Provide excellent patient care services
 - Acquire an accurate medication history
 - Make sure appropriate medications are ordered and utilized safely
 - Ensure that guidelines and restrictions are successfully utilized
 - Support the use of a comprehensive medication distribution service (oral and IV products prepared ready-to-administer)
 - Transfer medication information with your patient to colleagues
 - Educate, educate, educate
- Ensure that appropriate resources are always available



The Role of the Clinical Pharmacist

Manage your clinical service area

- Do know what medications are kept as floor stock?
- Do you know what other medications are kept in your area and where they are?
- Do you know if there are kits that contain medications in your areas? Where did they come from?
- Are any medications not labelled or secured appropriately?
- Where are patient's own medications stored? Are they used?

The Role of the Clinical Pharmacist

Participate on interdisciplinary teams and committees

- Medication Policy
- Medication Safety
- Quality and Quality Improvement
- Others

Communicate what you know and what you see

Special Populations

- What do you do for special populations? Are there any changes in practice or process to accommodate their needs? Many argue that all patients deserve the same level of care. But, is this true? What about...
 - Pediatric and neonatal patients?
 - Oncology patients?
 - Transplant patients?
 - Others?
- What about other (non-acute care) settings?
 - Ambulatory Care, Long-term care, home care, hospice

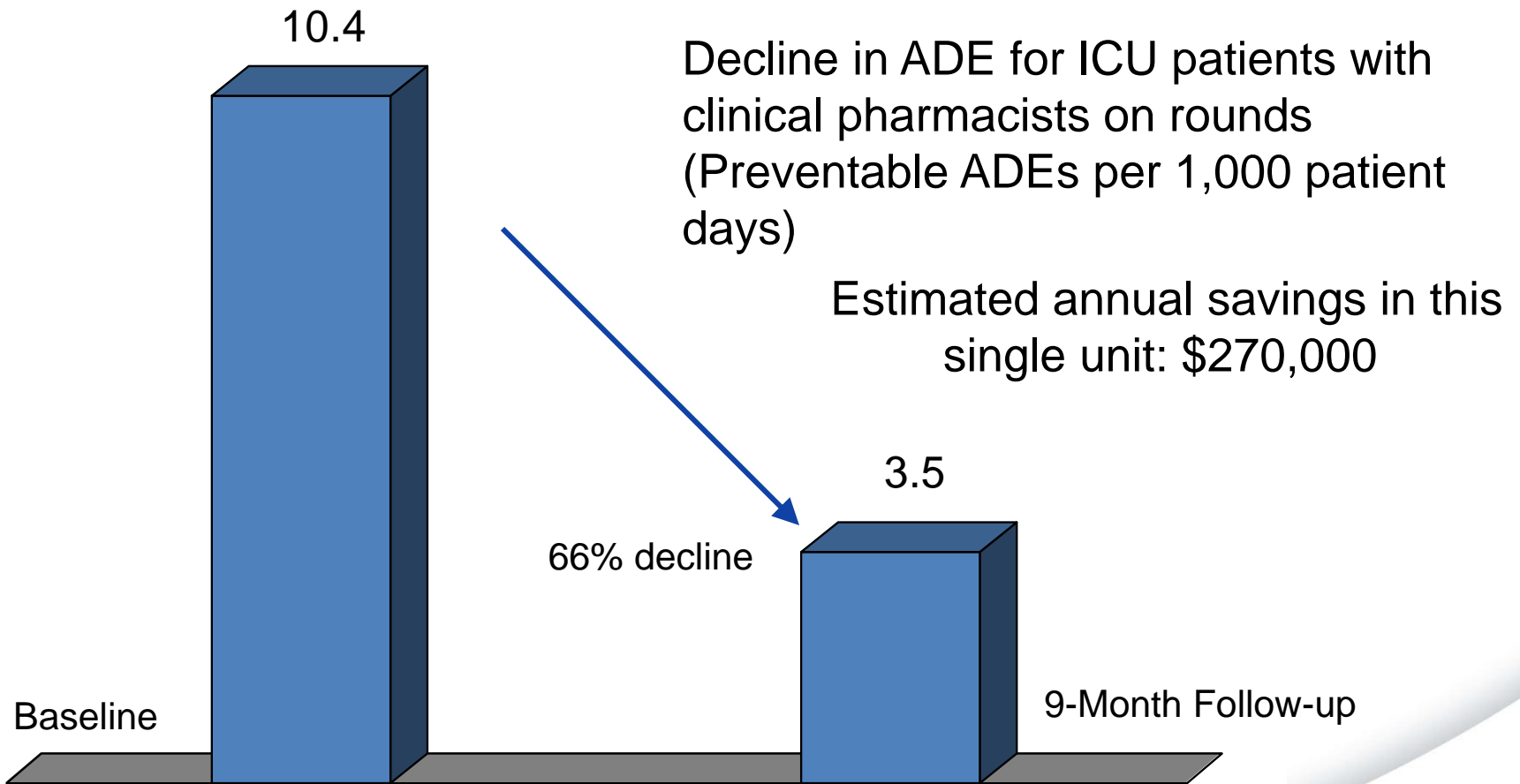
Roles of Other Pharmacy Colleagues

- Pharmacy technicians
- Pharmacy students
- Pharmacy residents
- Pharmacy couriers
- Other pharmacy employees

Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit

- Objective of study was to measure the effect of pharmacist participation on medical rounds in the ICU on the rate of preventable adverse drug events caused by ordering errors
- Controlled comparison at Massachusetts General Hospital MICU
- Senior pharmacist made rounds with team and was available in the ICU or on-call throughout the day
- Rate of preventable ordering ADEs decreased by 66% during study
- In 1995, if the cost of each preventable ADE due to error was \$4865, cost reductions of \$270K annually could be anticipated in this MICU alone

Value of ICU Clinical Pharmacy Services



Reducing Errors Through Discharge Medication Reconciliation by Pharmacy Services

- Objective of study was to determine whether integration of pharmacist review in the process of medication reconciliation at discharge identifies and corrects discrepancies.
- Study involved internal medicine patients cared for by hospitalist services at a 400-bed academic medical center
- 41% of patients had at least one medication discrepancy at discharge that can be identified and corrected by pharmacist intervention.
- Error types included duplication, omission, medication without indication, inappropriate medication for patient PK or allergy and formulary change not corrected.

The Clinical Pharmacist's Role in Working within a Safe Medication Use System



Basel Statements on the Future of Hospital Pharmacy

Select Overarching and Governance statements

- The responsible use of medicines means:
 - There is timely access to and the availability of quality medicine that is properly administered and monitored for effectiveness and safety.
 - A multidisciplinary collaborative approach is used that includes patients in addition to health professionals assisting in their care.

Basel Statements on the Future of Hospital Pharmacy

Select Overarching and Governance statements

- Hospital pharmacists should **take responsibility for the management and disposal of waste related to the medicine use process**, and advise on disposal of human waste from patients receiving medicines.
- Hospital pharmacists **should take responsibility for all aspects of selection, implementation and maintenance of technologies** that support the medicine use process, including distribution devices, administration devices, and other equipment.
- Hospital pharmacists should **ensure appropriate assessment, development, implementation and maintenance of clinical decision support systems and informatics that guide therapeutic decision making and improve the medicine use process.**

Basel Statements on the Future of Hospital Pharmacy

Select Overarching and Governance statements

- Each pharmacy should have contingency plans for medicine shortages and emergencies.

Select Influences on prescribing statements

- Hospital pharmacists should be key members of pharmacy and therapeutics committees to oversee all medicines management policies and procedures, including those related to off-label use and investigational medicines.
- Appropriately trained and credentialed hospital pharmacists should participate in collaborative prescribing.

Basel Statements on the Future of Hospital Pharmacy

Select **Preparation and delivery** statements

- Hospital pharmacists should **support the development of policies regarding the use or medicines brought into the hospital by patients**, including the evaluation of appropriateness of complementary and alternative medicines.

Select **Administration** statements

- Doses of chemotherapy and other institutionally-identified high-risk medicines should be **independently checked against the original prescription by at least two health care professionals, 1 of whom should be a pharmacist**, prior to administration.
- Hospital pharmacists should **ensure the development of quality assurance strategies for medicines administration to detect errors and identify priorities** for improvement.

Basel Statements on the Future of Hospital Pharmacy

Select **Administration** statements

- Hospital pharmacists should **develop and implement policies and practices that prevent route errors**. Examples include:
 - Labeling of intravenous tubing near insertion site to prevent misconnections;
 - Use of enteral feeding catheters that cannot be connected with intravenous or other parenteral lines;
 - Packaging vinca alkaloids to prevent inadvertent intrathecal administration;
 - Use of oral syringes that are distinctly different from hypodermic syringes to prevent injection of enteral or oral medicines.

Basel Statements on the Future of Hospital Pharmacy

Select **Monitoring** of medicines use statements

- An easily accessible reporting system for adverse drug reactions should be established and maintained.
- An easily accessible reporting system for medication errors, including near misses, should be established and maintained.
- Medicines use practices should be self-assessed and compared with benchmarks and best practices to improve safety, clinical effectiveness, and cost-effectiveness.
- Systematic approaches (trigger tools) should be used to provide quantitative data on adverse drug events and optimal medicines use. These data should be regularly reviewed to improve the quality and safety of medicines practices.

The ASHP Pharmacy Practice Model Initiative

- Invitational, consensus-seeking conference occurred in 2010
- The goal of the PPMI was to significantly advance the health and well-being of patients in hospitals and health-systems by development and disseminating optimal pharmacy practice models that are based on the effective use of pharmacists as direct patient care providers.

The ASHP Pharmacy Practice Model Initiative

- The objectives of the PPMI were to:
 - Describe optimal pharmacy practice models that ensure the provision of safe, effective, efficient, and accountable medication-related care for patients in hospitals and health-systems;
 - Identify core patient-care related services that should be consistently provided by departments of pharmacy;
 - Foster understanding of and support of optimal pharmacy practice models by patients and caregivers, health care professionals, health care executives, and payers.
 - Identify existing and future technologies required to support optimal pharmacy practice models.
 - Identify specific actions that pharmacists should take to implement optimal practice models.
 - Determine tools and resources needed to implement optimal pharmacy practice models.

The ASHP Pharmacy Practice Model Initiative

- 147 final points of consensus were developed at the summit
- Some key recommendations made during the summit:
 - All patients have the right to receive the care of a pharmacist.
 - Pharmacists must be responsible and accountable for patients' medication-related outcomes.
 - Every pharmacy department should develop a plan to reallocate its resources to devote significantly more pharmacist time to medication management services.
 - Pharmacists who provide drug therapy management services should be certified through the most appropriate board of pharmacy specialties.
 - In optimal pharmacy practice models, individual pharmacists must accept responsibility for both the clinical and the distributive activities of the pharmacy department.



Pharmacy Practice Model Initiative

Transforming how pharmacists care for patients

PPMI is a ***profession-led*** initiative that is **empowering** the pharmacy team to take responsibility for **patient outcomes**.

Care Team Integration	Leveraging Pharmacy Technicians	Pharmacist Credentialing & Training	Technology	Leadership in Medication Use
<ul style="list-style-type: none"> Promotes a team-based approach to health care Shifts the roles of the health care team to enable pharmacists to optimize their time with patients across the continuum of care Enhances the relationship between pharmacists and patients by positioning pharmacists as providers 	<ul style="list-style-type: none"> Empowers the pharmacy team to ensure that pharmacy technicians perform all traditional preparation and distribution activities Urges technicians to handle non-traditional and advanced responsibilities and activities to allow pharmacists to take greater responsibility for direct patient care Promotes technician training and certification requirements, such as the need for uniform standards for advanced technician roles 	<ul style="list-style-type: none"> Elevates the reputation of the pharmacy team Ensures pharmacists, residents, and students have training and credentials for activities performed within their scope of practice now and in the future Promotes the use of credentials to provide services at the top of the scope of practice 	<ul style="list-style-type: none"> Evaluates the available technologies to support patient safety and quality of care Encourages use of available automation and technology to improve patient safety, quality and efficiency, while also reducing costs Identifies emerging technologies to improve pharmacy practice 	<ul style="list-style-type: none"> Empowers pharmacists to take responsibility for patient outcomes Positions pharmacists to promote health and wellness, optimize therapeutic outcomes, and prevent adverse medication events Emphasizes that given their extensive education and training, pharmacists are integral in helping achieve the best outcomes

Transforming how pharmacists in acute and ambulatory settings care for patients

The Practice Advancement Initiative (PAI) is a **profession-led** initiative that is **empowering pharmacists** to take responsibility for **patient outcomes** in acute and ambulatory care settings.

Care Team Integration

- Promotes a team-based approach to health care
- Shifts the roles of the healthcare team to enable pharmacists to optimize their time with patients across the continuum of care
- Enhances the relationship between pharmacists and patients by positioning pharmacists as healthcare providers

Leveraging Pharmacy Technicians

- Empowers the pharmacy team to ensure that pharmacy technicians perform all traditional preparation and distribution activities
- Urges technicians to handle non-traditional and advanced responsibilities and activities to allow pharmacists to take greater responsibility for direct patient care
- Promotes technician training and certification requirements, such as the need for uniform standards for advanced technician roles

Pharmacist Credentialing & Training

- Elevates the reputation of the pharmacy team
- Ensures pharmacists, residents, and students have the training and credentials for activities performed within their scope of practice now and in the future
- Promotes the use of credentials to provide services at the top of the scope of practice

Technology

- Evaluates the available technologies to support patient safety and quality of care
- Encourages use of available automation and technology to improve patient safety, quality, and efficiency, while also reducing costs
- Identifies emerging technologies to improve pharmacy practice

Leadership in Medication Use

- Empowers pharmacists to take responsibility for patient outcomes
- Positions pharmacists to promote health and wellness, optimize therapeutic outcomes, and prevent adverse medication events
- Emphasizes that, given their extensive education and training, pharmacists are integral to achieving the best outcomes

2016-2017 Targeted Medication Safety Best Practices for Hospitals

- Best practices reviewed by an external expert panel and approved by the ISMP Board of Trustees
- Dispense vinCRISTine (and other vinca alkaloids) in a minibag of compatible solution and not in a syringe.
- Use a weekly dosage regimen default for oral methotrexate in electronic systems when medication orders are entered. And, require a hard stop verification of an appropriate oncologic indication for all daily oral methotrexate orders.
- Provide specific patient and/or family education for all oral methotrexate discharge orders.



2016-2017 Targeted Medication Safety Best Practices for Hospitals

- Avoid the use of stated, estimated or historical weight.
- Ensure that all oral liquids that are not commercially available as unit dose products are dispensed by the pharmacy in an oral syringe.
- Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization.
- Administer high-alert intravenous (IV) medication infusions via a programmable infusion pump utilizing dose error-reduction software.

2016-2017 Targeted Medication Safety Best Practices for Hospitals

- Ensure all appropriate antidotes, reversal agents, and rescue agents are readily available.
- Eliminate all 1,000ml bags of sterile water (irrigation, injection, inhalation) from all areas outside of the pharmacy.

The Role of the Clinical Pharmacist: Contribute to Safe Systems

- Support and foster a culture of safety
- Support the medication policy and medication safety processes
- Support the implementation and use of established medication policy and medication safety practices
- Participate in the evaluation of the medication-use system (e.g. routine MUE and ISMP Self-Assessment, etc.)
- Support department and organizational initiatives



Role of Controlled Formulary in Safety

A formulary helps to promote the safe use of medications

- Systems to evaluate medication selection promote the safe use of medications
- Medication-use evaluation helps promote the safe use of medications
- Guidelines help to promote the safe use of medications
- Restrictions help to promote the safe use of medications

Role of Controlled Formulary in Safety

- Limiting choices; increasing standardization
- Evaluation of product packaging, labeling, LASA, as a routine component of formulary review
- CPOE forcing functions
 - Limit dosing choices
 - Make it easy to do the “right thing”
 - Use clinical decision support tools

Contribute to Safe Systems

A medication safety program helps to promote the safe use of medications

- Systems to facilitate anonymous, easy reporting of events
- Event analysis and trending helps promote the safe use of medications
- Sharing event trends and lessons learned helps to promote the safe use of medications
- Reporting events to agencies helps to promote the safe use of medications
- Participation on event analysis efforts is a core clinical pharmacist role



Error Reporting and Detection

- Medication error reporting systems
 - Voluntary systems typically capture only 5%; mandatory reporting systems may stifle reporting and create fear/legal liability
 - Should capture actual errors and near misses
 - Should uncover hazards and trends
 - Ideally error reduction strategies are implemented based on serious errors or patterns of errors
 - Attempt to have all personnel report as soon as possible after event (closest to incident), although most reports by nurses and pharmacists

Safe practices that reduce errors

- Use standardized concentrations for IV medications
- Use commercially available solutions when possible
- Dispense in ready to administer form when possible
- Do not keep concentrated electrolytes outside of the pharmacy
- Special attention to “high-alert” medications
- Use technology whenever possible to reduce errors – in prescribing, dispensing and administration

Ready to use packaging

- Research has shown that unit dose packaging reduces medication errors during dispensing and medication errors when administering to patients.
- Unused medications can be returned to the pharmacy and easily dispensed again for another patient.
- The integrity of the drug can be assured because it is in a sealed container.

Why IV products should be prepared in the pharmacy

- A controlled, sterile preparation area can be used within a laminar flow hoods in a segregated space.
- Pharmacy technicians can receive special training in aseptic technique and calculations.
- Pharmacists can supervise and observe how products are prepared.
- Dosage calculations and medications can be verified for accuracy by the pharmacist.



IV Medication Safe Practices



Heparin infusion Magnesium infusion

Removing concentrated potassium and making available as a premixed solution.

Standardized, manufacturer-prepared solutions reduce calculation and preparation errors.



Future Initiatives

- Standardized concentrations for hospitals, health-systems, and on larger scales
 - Oral products
 - Sterile products
 - Adult populations
 - Pediatric and neonatal populations

**Pharmacist Roles in
Promoting Safe and Effective
Use of Medication-Related
Automation and Technology**



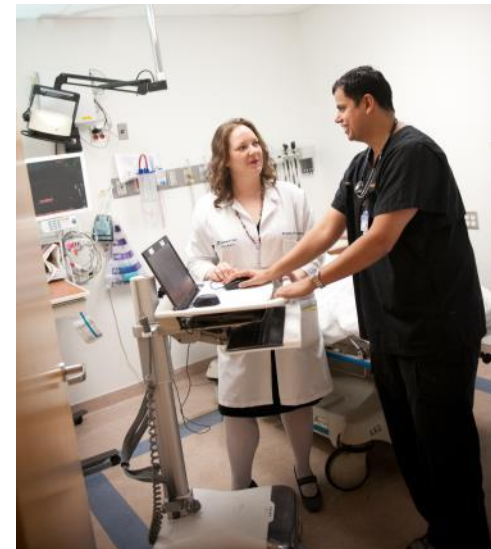
Automation of Medication Use Process

- Traditional System
 - Ordering: written, on paper
 - Transcription: manual
 - Dispensing: manual
 - Administration: manual
 - Recording: manual, on paper
- Automated System
 - Ordering: CPOE
 - Transcription: none
 - Dispensing: ADC/robotics
 - Administration: BCMA
 - Recording: eMAR

Least safe



Most safe

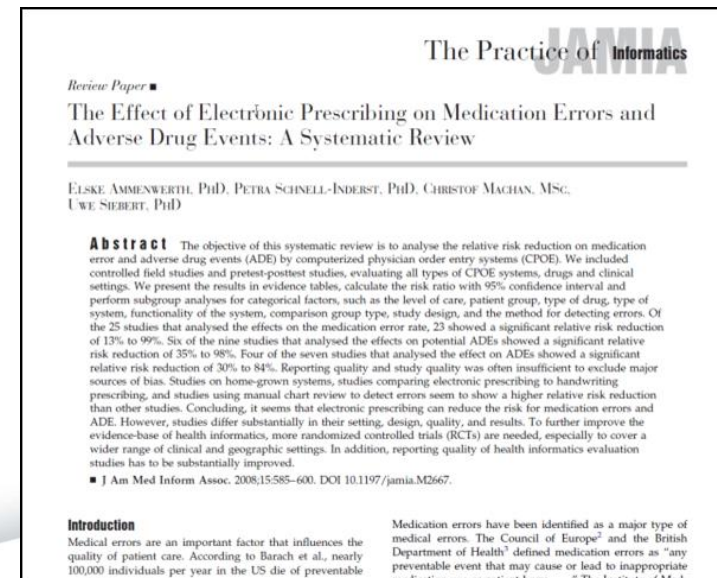
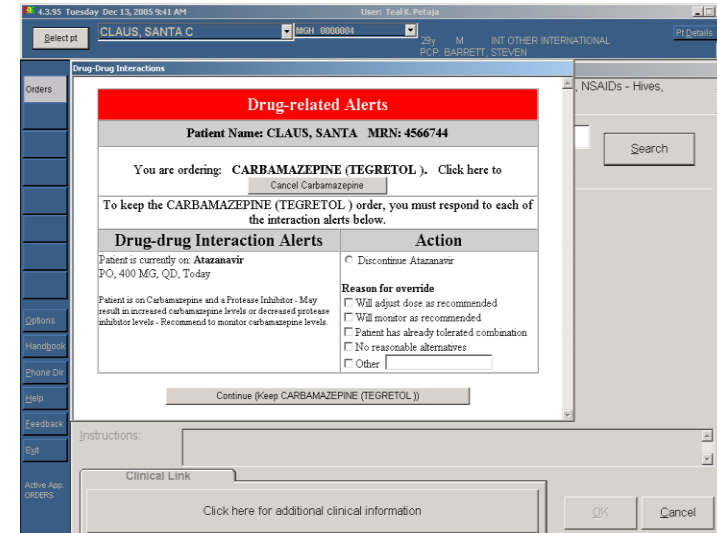


Automation/Technology to Minimize Errors

- **Ordering** – CPOE, clinical decision support, eliminate transcription
- **Dispensing** – bar coding, robotics, automated dispensing cabinets with profile review, end product testing
- **Administering** – eMAR, BCMA, “smart” pumps
- **Monitoring** – pulse oximetry, capnography, clinical decision support/surveillance
- **Goal of moving toward *zero errors***

Computerized Prescriber Order Entry

- Clinical decision support/alerts
 - Rules (out of box vs. custom)
 - Weight based dosing
 - Hard stops for allergies, weights
- Pharmacy review
- Systematic review of CPOE
 - Reported on 27 published studies meeting criteria
 - Many systems, study periods
 - Overall risk reduction in medication errors
 - Overall risk reduction in potential ADEs
 - Overall risk reduction in ADEs



Automation/Technology in Dispensing

- Use of automated dispensing cabinets or robotics
- Improves safety, accuracy of dispensing
- Improves efficiency
- Shifts distribution away from pharmacist, allows pharmacist more time for patient care services and focus on safety



Bar Code Medication Administration

- Research on impact of BCMA
 - 11.5% error rate with non-BCMA doses
 - 6.8% error rate with BCMA doses (41.4% reduction)
 - 83% reduction in errors of administration documentation
 - 57% reduction in wrong medication errors
 - 42% reduction in errors of wrong dose



What is the Clinical Pharmacist's Role?

- Participate in the oversight of the systems used in your patient care areas: own every process and every issue
- Collaborate with physicians, nurses and other health-care professionals (e.g., respiratory therapists, etc.) to make sure that processes are maximized (IT systems and automated systems)
 - Help write standard sets that meet all safety parameters
 - Help make sure that bar codes and automated systems work
- Participate in the oversight of pharmacy technicians that work with these systems

Thank you.



The Clinical Pharmacists' Role in Patient Safety

David J. Warner, Pharm.D.

Director, Center on Practice Development

ASHP Consulting

