ISMP International Forum on Patient Safety

The Use of Clinical Evidence to Reduce Medication Errors and Adverse Drug Events

Jill Sutton SVP Product Management
Agenda

- Truven Health Analytics Overview
- The problem of medication errors and adverse drug events (ADEs)
- Challenges in incorporating evidence into clinical practice
  - Finding the best evidence
  - Accessing the right evidence within workflow
- Current decision support tools available to improve outcomes and patient safety
- Questions
OUR VISION

To improve the quality and lower the cost of healthcare through the better use of data and analytics.

OUR MISSION

To reveal meaningful insights and identify unseen opportunities in healthcare so that our customers realize tangible value.
Adverse Drug Events are Happening Right Now In Healthcare Settings World-wide

- Approximately **1.5 million preventable adverse drug events** occur in the United States each year.
- Each Preventable ADE adds about **$8,750** to the cost of the hospital stay.
- **400,000 events x $8,750 = ~$3.5 billion**, annually.

*These costs do not account for lost earnings or compensation for pain and suffering*

*Preventing Medication Errors, Board on Healthcare Services, Quality Chasm Series, Institute of Medicine of the National Academies, 2007*
A FORMULA FOR SUCCESS: THE CDS FIVE RIGHTS

To improve care outcomes with CDS you must provide:

- the **Right Information**…
  Evidence-based, useful for guiding action and answering questions

- …to the **Right Stakeholder**…
  Both clinicians and patients

- …in the **Right Format**…
  Alerts, Order Sets, answers, etc.

- …through the **Right Channel**…
  Internet, mobile devices, clinical information systems

- …at the **Right Point in the Workflow**
  to influence key decisions/actions
# A Deeper Dive into Medication Management

## Medication Management

### WHEN: Reconcile/Select
- **WHO:**
- **WHAT:** Drug, Disease, Recommendations References
- **HOW:** Order Sets, Reference
- **WHERE:** EMR, Online, Mobile, Surveillance
- **WHY:** Optimize EBM, Quality, Regulatory, Cost, Safety

### WHEN: Administer
- **WHO:**
- **WHAT:** Reference Info: Administration, IV Compatibility
- **HOW:** Reference
- **WHERE:** eMAR, EMR, Bar Coding
- **WHY:** Safe Administration

### WHEN: Prescribe/Order
- **WHAT:** Order Sets and Drug References
- **HOW:** Reference, Order Sets/Checks
- **WHERE:** EMR, Online, Mobile, Order Forms
- **WHY:** Safer Use: DDI, dosing, allergies

### WHEN: Educate
- **WHAT:** Patient Instructions and Education
- **HOW:** Reference
- **WHERE:** Online, EMR, PHR
- **WHY:** Optimize Patient Self Care

### WHEN: Verify/Dispense
- **WHAT:** Reference, Alerts on Dosing/Interactions
- **HOW:** Reference, Alerts
- **WHERE:** Pharmacy System, Online, EMR
- **WHY:** Safety, Appropriateness Check

### WHEN: Monitor
- **WHAT:** Reference Drugs, Disease (course), Labs, Effect Monitoring
- **HOW:** Reference, Rule Checking, Alerts
- **WHERE:** EMR, Surveillance, PHR, Online
- **WHY:** Track Effects
How do clinicians practice EBM?

1. Transform the need for information into an answerable question (prevention, therapy, diagnosis, prognosis)

2. Gather the best evidence to answer the question

3. Critically evaluate the evidence for its validity, impact, and applicability

4. Translate the evidence into clinical practice by integrating it with clinical expertise and the patient’s values, biology and circumstances

Integrating Evidence into Workflow

Finding the Best Evidence
Information Overload!

- Too much literature to filter:
  - 12,000 articles are added to MEDLINE per week

- Low-quality information drowns out high-quality information

- Cannot find data the right data for a patient’s specific needs
Evaluating the Evidence

Clinicians must critically evaluate the methodological rigor and statistical analyses of a study,

But…

- No time to master required skills
- Time spent with each patient is limited to a few minutes
How confident can we be in the evidence?

- Not all evidence is equally convincing

- How convincing the evidence is should be determined by:
  - What sort of observations (study design)
  - How well they were done (risk of bias)
  - How consistent they are (consistency)
  - How directly relevant they are (directness)
  - How many there are (precision)
  - How strong an association is (large effects)

NOT on who says it or how they say it
“The medical literature can be compared to a jungle. It is fast growing, full of dead wood, sprinkled with hidden treasure and infested with spiders and snakes.”

Peter Morgan, Scientific Editor, Canadian Medical Association
### Key Considerations when evaluating Clinical Decision Support Resources

<table>
<thead>
<tr>
<th>Category</th>
<th>Consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Literature surveillance</td>
<td>• Processes in place to continuously monitor the <em>full body of medical literature</em></td>
</tr>
<tr>
<td>Literature evaluation and selection</td>
<td>• Defined process for editors to receive <em>ongoing literature evaluation training</em></td>
</tr>
<tr>
<td>Description of the studies used:</td>
<td>• Study details to help clinicians <em>correlate study results to their specific patient</em></td>
</tr>
<tr>
<td>Transparency of supporting evidence/ references</td>
<td>• In-line references throughout to evaluate the quality of evidence and seek further detail if necessary</td>
</tr>
<tr>
<td>Ratings/Recommendation</td>
<td>• Evidence ratings for every indication to make recommendations (ratings) supported by the evidence (references) to assist clinicians in decision making.</td>
</tr>
</tbody>
</table>
Evidence-based Information is Foundational to Delivering High Quality Clinical Decision Support

We include the **best** of the available medical literature in our content

- **Rigorous Literature Evaluation Policy**
  - Evaluation of the quality of the study so that only the best evidence is incorporated into Micromedex content
  - Determination of clinical significance of the study drives update prioritization
  - Conflict of Interest Policy to protect against outside influence

**TRIAGE AND REVIEW BY SENIOR CLINICIANS**

**APPLY LITERATURE INCLUSION/EXCLUSION CRITERIA**

**SENIOR CLINICIANS SELECT LITERATURE FOR CONTENT**
Can risperidone be used to treat post-traumatic stress disorder (PTSD)?

Study strengths

- Very strong design: randomized, double-blind, placebo-controlled trial

Study limitations

- Small number of patients (37 patients with less than 20 patients per group)
- Precision, or confidence in the results, may be limited by the small number of participants
- “Preliminary results” that warrant further study of risperidone according to the authors

Findings

- Risperidone-treated patients showed a significantly greater decrease from baseline, albeit modest, in psychotic symptoms (PANSS total scores) than placebo-treated patients (P < 0.05). CAPS ratings declined significantly in both groups but did not differ significantly between the risperidone and placebo groups.

Bottom line: These are preliminary results and the groups may be too small to produce findings with adequate precision to be confident in the finding or detect a difference between the groups.
Is sertraline effective for treating bipolar affective disorder?

Study strengths

- Very strong design: 10-week, randomized, double-blind trial with patients randomized to treatment with bupropion, sertraline and venlafaxine, or their respective matching placebos, as adjuncts to mood stabilizers

Study limitations

- Small number of patients in each treatment arm (total of 174 study participants)
- No discussion on the number of patients required to detect a difference between arms
- High drop out rate (ranged from 31% to 45% for each arm)
- According to the authors, with the absence of a placebo arm, we do not know with any degree of certainty whether any of the antidepressants was efficacious, i.e. significantly more effective than placebo.
  - Nemeroff et al (2001) found that the effectiveness of paroxetine did not exceed that of placebo when used as an adjunct to lithium

Findings

- There were no differences in response rates or remission rates

Bottom line: Interpret with caution since the study was not powered and small sample size may decrease the precision of the results. There were also high dropout rates which could dilute treatment effects and lead to no differences.
Evidence Ratings in Information Resources

Micromedex® 2.0 | Dispositivo Móvel

Overview
Dosing Information
- Drug Properties
- Storage and Stability
- Adult Dosage
- Pediatric Dosage
Pharmacokinetics
- Onset and Duration
- Drug Concentration Levels
- ADM E
Caution
- Black Box Warning
- Contraindications
- Precautions
- Adverse Reactions
- Teratogenicity/Effects in Pregnancy/Breastfeeding
- Drug Interactions
Clinical Applications
- Monitoring Parameters
- Patient Instructions
- Place in Therapy
- Mechanism of Action/Pharmacology
- Therapeutic Uses
- Comparative Efficacy/Evaluation With Other Therapies
References

Thrombolytics: Clopidogrel (Plavix®)

Clinical Applications

Drug Consults

Response

The Thomson Efficacy: Strength of Evidence and Strength of Recommendation definitions are outlined below:

- Table 1: Strength of Recommendation
  - Class 1: Recommended
  - Class 2a: No Consensus
  - Class 2b: Recommended, In Some Cases
  - Class 2c: No Consensus, In Some Cases
  - Class 3: Indeterminate/Evidence Inconclusive

- Table 2: Strength of Evidence
  - Category A: Evidence is based on data from: Meta-analyses of randomized controlled trials with homogeneity and effect measured in the same way results combined in a meta-analysis
  - Category B: Evidence is based on data from: Meta-analyses of randomized controlled trials with conflicting conclusions regarding the direction or degree of results between individual studies
  - Category C: Evidence is based on data from: Expert opinion or consensus, case reports or case series

- Table 3: Efficacy
  - Class I: Effective
  - Class IIa: Effective and/or expert opinion suggests that a given drug treatment for a specific indication is effective
  - Class IIb: Evidence favors efficacy
  - Class IIIa: Ineffective
  - Class IIIb: Indeterminate/Evidence Inconclusive
  - Class IIIc: Ineffective and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective

References

©2012 Truven Health Analytics, Inc.
INTEGRATING EVIDENCE INTO WORKFLOW

USE OF INNOVATIVE TECHNOLOGIES

TO IMPROVE OUTCOMES
What Keeps Clinicians From Directly Impacting Patient Care?

Data in multiple systems or not accessible within workflow. Incomplete information about patients

Quality Improvement
Medication Management
Infection Prevention

Clinician
THE PROBLEM

- When treating patients, clinicians have many questions
  - Many questions go unanswered
  - Clinical questions vary and are complex
  - Clinicians spend less than 30 seconds attempting to find information outside their workflow

- Reasons that questions are not answered
  - Excessive time required to find information
  - Difficulty modifying question/searching in resources
  - Abundance of information/difficulty in selecting sources
  - Not in clinicians’ workflow

Clinicians need relevant information provided in their workflow so they can focus on their patients needs
The Solution is to Integrate Evidence into Workflow

HIS Integration

- Infobutton Webservice
  - Drug Point
  - Disease Summary
  - Lab Advisor

- CN HIS Integration Webservice

Stand-Alone

MDX UI

- Drug Dex
- Disease Dex
- Lab Advisor
  - PoisinDex
  - IV Index
  - AltMedex
  - DrugReax
  - Calculators

Care Notes

- Drug Notes
  - Care and Condition
  - Lab Notes
INTEGRATED CLINICAL KNOWLEDGE
Integrating Evidence Into Clinical Workflow

- InfoButton provides access to evidence-based content from an electronic medical record, order entry system, portal or other Information system application

- InfoButton Access:
  - Saves time by reducing steps that clinicians take to find information – No longer have to log out of one application and into another.
  - The ease of use encourages clinicians to get answers to questions more frequently and accurately – leading to better patient care.
  - InfoButton Access simplifies the process of searching for clinical reference information.
INFOBUTTON SOLUTION

DOE, JANE

Attending: Dr. Bonebreak  MRN: 89VN76  Unit/Room/Bed: 3W/102/1

Race: WHITE  Birthdate: 01/10/1966  ADM:

Diagnosis: Dermatomyositis

Vital Signs

Height: 5'6"  Ft  Cm
Weight: 136  lb  Kg
Temp: 99.5  °F  °C

Encounter Information

Problem List

- Dermatomyositis
- Community Acquired Pneumonia
- Hypertension

Allergy

Penicillin

Turn off Allergy Color Coding

Hypertension - Prevention & Screening

Definition

An elevated systolic blood pressure (SBP) of 140 mmHg or higher or a diastolic BP (DBP) of 90 mmHg or higher, taking antihypertensive medications, or being instructed twice by a physician or other health professional that you have high blood pressure.

Screening Criteria

- Adults with normal blood pressure (less than 120/80 mmHg) should be screened every 1 to 3 years.

Prevalence of hypertension:

- Children over three years of age should have their blood pressure (BP) measured at least once during every healthcare episode that is assessed in a medical care setting.

Truven Health Analytics, Inc.
CPOE Workflow Example

MARY DAVIS, RN
01/15/03

Patient Assignment: Patient 3 of 5

Admit Date: 1/15/03
Admit Diagnosis: Hip Pain
Insurance: MEDICARE
Prim. Care Phys.: Dr. Joe Anderson

ER Patient Flowsheet

History

Medication | Strength | Dose | Route | Freq | Last
--- | --- | --- | --- | --- | ---
Furosemide | 20 mg tabs | 20 mg | PO | qd | 01/14/03 09:15
Lisinopril | 10 mg tabs | 10 mg | PO | qd | 01/14/03 09:15
Plavix | 75 mg tabs | 75 mg | PO | qd | 01/14/03 09:15
Prevacid | 15 mg caps | 15 mg | PO | qd | 01/14/03 09:15
Digoxin | 0.25 mg tabs | 0.25 mg | PO | qd | 01/14/03 09:15

inued Medications

Lipitor | 10 mg tabs | 10 mg | PO | qd | 01/14/03 09:15
Digoxin | 0.25 mg tabs | 0.25 mg | PO | qd | 01/14/03 09:15
### Example of UltiMedex Results Configuration for Warnings

<table>
<thead>
<tr>
<th>PRN</th>
<th>Route</th>
<th>Med/Ingredient</th>
<th>Strength</th>
<th>Amount To Give</th>
<th>Schedule</th>
<th>Start</th>
<th>Renew</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-M</td>
<td>Oral</td>
<td>DIAZEPAM</td>
<td>2 MG</td>
<td>One tablet</td>
<td>Q4H</td>
<td>5/1 14:09</td>
<td>5/1 14:09</td>
</tr>
<tr>
<td>P-M</td>
<td>Oral</td>
<td>TYLENOL W/CODEINE</td>
<td>300 MG-6...</td>
<td>One tablet</td>
<td>Q4H</td>
<td>9/27 09:31</td>
<td>9/29 09:31</td>
</tr>
<tr>
<td>S-I</td>
<td>100 ml/hr</td>
<td>DEXTROSE</td>
<td>5%</td>
<td>1000 ml</td>
<td>CONTINUOUS</td>
<td>5/1 13:57</td>
<td>5/1 13:57</td>
</tr>
<tr>
<td>S-I</td>
<td>33 ml/hr</td>
<td>CIPRO IV</td>
<td>400 MG/2...</td>
<td>400 mg</td>
<td>Q12H</td>
<td>5/2 12:00</td>
<td>5/2 12:00</td>
</tr>
<tr>
<td>S-M</td>
<td>Oral</td>
<td>STALEVO 100</td>
<td>25 MG-20...</td>
<td>1 tablet</td>
<td>Daily</td>
<td>9/1 16:12</td>
<td>9/1 16:12</td>
</tr>
<tr>
<td>S-M</td>
<td>Oral</td>
<td>METOCLOPRAMIDE HY...</td>
<td>10 MG</td>
<td>10 MG</td>
<td>QID</td>
<td>9/1 16:13</td>
<td>9/1 16:13</td>
</tr>
</tbody>
</table>
Next Generation Systems: Real-Time Patient Analytics

- Solutions that monitor clinical conditions and predict potential adverse events in real-time and deliver patient-specific information at the point of care
  - Include clinical decision support rules based on best available evidence
  - Push relevant actionable information to clinicians
  - Help clinicians focus their attention on the needs of patients and intervene earlier than they might have otherwise.
  - Highly impactful for influencing clinical decisions and standardizing care
CLINICAL PERFORMANCE IMPROVEMENT (CPI) PLATFORM

CLINICAL DATA FOUNDATION
- Vitals
- Active Orders
- Reports
- Leverage existing hospital information systems
- Real-time data acquisition
- Clinical data acquisition

PATIENT-CENTRIC, ACTIONABLE DECISION SUPPORT
- Micromedex Evidence
- CDS Rules
- Clinical content

UNIQUE USERS, UNIQUE NEEDS
- Pharmacist
- Infection Preventionist
- Nurse
- Quality Assurance
- Physician

CLINICAL XPERT SOLUTIONS
- Pharmacy XPERT
- Infection XPERT
- Carefocus
- Clinical XPERT Navigator
- Patient XPERT
Event-Driven systems should use industry-standard interfaces for predictable implementations and long-term stability.
Clinical Dashboard

- Single click access to H.I.S and other resources
- Quick view of critical values with automated interaction checking and pharmacy tools and calculators
- Easy documentation of intervention within the workflow
- Real-time surveillance of at-risk patients
- Comprehensive medication, lab and report information – with integrated access to evidence-based content
Renal Monitoring

- Renal monitoring algorithms find patients with decreased renal function on specific medications.
- Dosage adjustments are often required in patients with renal dysfunction to prevent adverse effects and improve patient outcomes.
- The system identifies patients on the specified drugs, continually monitors lab values such as creatinine clearance or serum creatinine in real time.
- Alerts clinician if patient on that drug has lab values indicating a dose adjustment is needed. The parameters and dosing adjustments are based on evidence.
Reduce Risk: A Proactive Approach

Empower Bedside Clinicians with Real-time Clinical Improvement Loop

Clinical Action

Locate Risk

Prevent Avoidable Events

Identify Improvement Opportunity

Evidence Based Solutions

• Real-time Data
• Clinical Dashboards

• CDS Rules
• Alerts
• Interactions
• Knowledge Resources
• Patient Education

• Track Interventions
• Data Analysis Tools
• Reporting Tools

Empower Bedside Clinicians with Real-time Clinical Improvement Loop

Clinical Action

Locate Risk

Prevent Avoidable Events

Identify Improvement Opportunity

Evidence Based Solutions

• Real-time Data
• Clinical Dashboards

• CDS Rules
• Alerts
• Interactions
• Knowledge Resources
• Patient Education

• Track Interventions
• Data Analysis Tools
• Reporting Tools
Quality, One Patient at a Time

- Leverage tools that provide and integrate the best evidence tailored to your patient’s unique needs
- Consider single solutions that provide consistency across multiple departments
- Reduce risk through a proactive approach to patient care