Clinical Interventions in Australian Community Pharmacies (The PROMISE Project)

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Background

• Clinical Intervention
  – The process of identifying an actual or potential drug related problem and recommending an action to be taken to resolve or prevent the problem

• Frequency, Type and Value of clinical interventions in Australian community pharmacies is not clearly known
PROMIS-e Method

- Developed a Classification System
  - DOCUMENT
    - Type/Subtype, Action, Recommendation, Clinical Significance, Outcome

- Developed an electronic data collection system
  - Central repository model

- Tested the effect of Remuneration, an Intervention Prompt, and Observation

- Undertook an Economic Analysis
A Classification System for DRPs and their resolution

- **Type/Subtype**
  - Drug Selection
    - eg. Contraindication, duplication, interactions
  - Over/Underdose
  - Compliance
  - Undertreatment
  - Monitoring
  - Education
  - Non-clinical
  - Toxicity/ADRs

- **Action**
  - Discussion, resources

- **Recommendation**
  - Drug/dose change, referral, education

- **Clinical Significance**

- **Outcome**
  - Acceptance of recommendation

Online validation by >200 independent pharmacists and ~150 PROMISe pharmacists

Method: Electronic Data Collection

- Intervention recording system installed into WiniFRED® dispensing program with secure, de-identified data transfer to a repository

Pharmacy:
- Dispense System
  - WiniFRED
  - PROMISe Interface
  - Record Intervention Info
  - HL7 Message Building

CommServer:
- PKI Encryption
- Transmission of data

Communication:
- HL7:
  - Encrypted HL7 Intervention
- PKI:
  - PKI Encryption
- SMIME Packeting:
  - Data Transmission

Secure Firewall:
- Authorised access only

PROMISe Server:
- User Authentication
- PKI Decryption
- HL7 Structure Rule Checks
- HL7 Business Rule Checks

Database:
- De-identified Intervention repository
WiniFRED® PROMISE®

Interface

- Information from prescription entered automatically
- Other information relating to intervention added by pharmacist
Methods: PROMISe Data Collection

- Recorded and documented aspects of:
  - Pharmacy Demographics
    - Daily workload and staffing
    - Entrepreneurial orientation
    - Prescriptions dispensed
  - Pharmacist Demographics
    - Clinical skills
    - Job satisfaction
  - Clinical Intervention Parameters
    - Patient demographics
    - Drug involved and other drugs taken by patient
    - Type of problem
    - Action taken, Recommendation made
    - Acceptance of recommendation
    - Reactive or proactive
    - Time taken

Analysis
- Frequency and relationships
- Drugs involved
- Effect of
  - Remuneration,
  - Observation and
  - Intervention Prompt
- Economic
Pharmacy Recruitment and Enrolment

- 52 pharmacies in a 100km radius of central Melbourne
- Pharmacies were representative of Australian pharmacies
Results: Frequency of Interventions

2396 interventions from 435,520 scripts and 258,979 patient encounters

Average
0.92 interventions per 100 patients
0.55 interventions per 100 scripts
<table>
<thead>
<tr>
<th>Category</th>
<th>Subcategory</th>
<th>Number</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug selection</td>
<td>Duplication</td>
<td>83</td>
<td>3.46%</td>
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<tr>
<td>Drug selection</td>
<td>Drug interaction</td>
<td>58</td>
<td>2.42%</td>
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<tr>
<td>Drug selection</td>
<td>Wrong drug</td>
<td>120</td>
<td>5.01%</td>
</tr>
<tr>
<td>Drug selection</td>
<td>Wrong dosage form</td>
<td>98</td>
<td>4.09%</td>
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<tr>
<td>Drug selection</td>
<td>Other drug selection problem</td>
<td>186</td>
<td>7.76%</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>2396</strong></td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Over or underdose prescribed</td>
<td>Dose too high</td>
<td>178</td>
<td>7.43%</td>
</tr>
<tr>
<td>Over or underdose prescribed</td>
<td>Dose too low</td>
<td>169</td>
<td>7.05%</td>
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<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>2396</strong></td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Compliance</td>
<td>Taking too little</td>
<td>117</td>
<td>4.88%</td>
</tr>
<tr>
<td>Compliance</td>
<td>Taking too much</td>
<td>48</td>
<td>2.00%</td>
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<tr>
<td>Compliance</td>
<td>Intentional drug misuse</td>
<td>12</td>
<td>0.50%</td>
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<tr>
<td>Compliance</td>
<td>Difficulty using dosage form</td>
<td>44</td>
<td>1.84%</td>
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<tr>
<td>Compliance</td>
<td>Other Compliance Problem</td>
<td>54</td>
<td>2.25%</td>
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<tr>
<td>Untreated indications</td>
<td>Condition not adequately treated</td>
<td>97</td>
<td>4.05%</td>
</tr>
<tr>
<td>Untreated indications</td>
<td>Preventive therapy required</td>
<td>266</td>
<td>11.10%</td>
</tr>
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<td></td>
<td><strong>Total</strong></td>
<td><strong>2396</strong></td>
<td><strong>100%</strong></td>
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<tr>
<td>Monitoring</td>
<td>Laboratory Monitoring</td>
<td>15</td>
<td>0.63%</td>
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<tr>
<td>Monitoring</td>
<td>Non-Laboratory monitoring</td>
<td>23</td>
<td>0.96%</td>
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<tr>
<td>Monitoring</td>
<td>Other Monitoring Problem</td>
<td>9</td>
<td>0.38%</td>
</tr>
<tr>
<td>Education or Information</td>
<td>Patient drug information request</td>
<td>87</td>
<td>3.63%</td>
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<tr>
<td>Education or Information</td>
<td>Confusion about therapy</td>
<td>120</td>
<td>5.01%</td>
</tr>
<tr>
<td>Education or Information</td>
<td>Demonstration of device</td>
<td>62</td>
<td>2.59%</td>
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<tr>
<td>Education or Information</td>
<td>Disease management or advice</td>
<td>89</td>
<td>3.71%</td>
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<td></td>
<td><strong>Total</strong></td>
<td><strong>2396</strong></td>
<td><strong>100%</strong></td>
</tr>
<tr>
<td>Non Clinical (see elsewhere)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Toxicity or Adverse reaction</td>
<td>Toxicity caused by dose</td>
<td>17</td>
<td>0.71%</td>
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<tr>
<td>Toxicity or Adverse reaction</td>
<td>Toxicity caused by drug interaction</td>
<td>87</td>
<td>3.63%</td>
</tr>
<tr>
<td>Toxicity or Adverse reaction</td>
<td>Toxicity evident</td>
<td>129</td>
<td>5.38%</td>
</tr>
<tr>
<td>Toxicity or Adverse reaction</td>
<td>Other Toxicity/Adverse Effect problem</td>
<td>31</td>
<td>1.29%</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>2396</strong></td>
<td><strong>100%</strong></td>
</tr>
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</table>

- **Types of Problems Detected**

  - **D** - Drug selection: 22.7%
  - **C** - Compliance: 11.5%
  - **U** - Untreated indications: 15.9%
  - **E** - Education or Information: 17.4%

Total: 100%
Raw number of drugs involved with CIs only tell part of the story- drugs are more or less frequently dispensed
Unique data: Can also determine common types of intervention for each group of medications
Economic Methods: Determining the Value of Interventions

• Developed a unique system involving expert assessment of the **probability** of both positive and negative consequences, at different levels of severity, both with and without the intervention.

• Secure internet access to intervention details 16 Clinical Assessors in 4 virtual panels of 4
  – 2 physicians, 6 GPs, 8 pharmacists
# Economic Methods: Consequences Table

## Consequences Table

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Health Status Impact</th>
<th>Dur’n of Health Status Impact</th>
<th>Duration of Admis’sn</th>
<th>Cost of Admis’n</th>
<th>No. of GP Cons.</th>
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<tbody>
<tr>
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<tr>
<td>05.02Mild</td>
<td>1</td>
<td>360</td>
<td>0.00</td>
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<tr>
<td>05.02Moderate</td>
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## Diagram Description

- **PROMISE Dataset of Clinical Interventions**
- **Sample of Clinical Ints**
- **Consequences Table (Value of each consequence)**
- **Selection and assessment of probability**
- **Before and After Probabilities**
- **Value of Difference in Probabilities**
- **Extrapolation**
- **Expert Assessment Panel Members**
- **Value of Sample of Clinical Ints**
- **Attribution**

### Table Notes
- **Subgroup Severity Description**
  - Mild signs or symptoms which resolve without intervention
  - Moderate elevation of blood pressure requiring modification of or commencement of medical management
  - Acute injury to target organs (e.g. renal, ocular or cerebral) requiring prompt medical management
  - Occult gastrointestinal bleeding likely to require medical management only if persistent
  - Overt gastrointestinal bleeding requiring medical management
  - Overt gastrointestinal bleeding with haemodynamic consequences requiring admission to hospital and prompt medical management
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<thead>
<tr>
<th>MDC Code</th>
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<tr>
<th>MDC Code</th>
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</table>
Methods: Assessment of Value

Multiple experts assign **before** and **after** probabilities for multiple different consequences (A, B, C etc.) at different levels of severity (Severe, Moderate, Mild)

Cerebrovascular event shown as an example of Consequence A

\[
\left( \text{Probability of Severe Consequence A Before Cl} \right) - \left( \text{Probability of Severe Consequence A After Cl} \right) = \text{Difference in Probability of Severe Consequence A}
\]

- **e.g.** Stroke, resulting in hospitalisation and requiring medical management

\[
\left( \text{Probability of Moderate Consequence A Before Cl} \right) - \left( \text{Probability of Moderate Consequence A After Cl} \right) = \text{Difference in Probability of Moderate Consequence A}
\]

- **e.g.** Neurological deficit requiring medical attention and investigation

\[
\left( \text{Probability of Mild Consequence A Before Cl} \right) - \left( \text{Probability of Mild Consequence A After Cl} \right) = \text{Difference in Probability of Mild Consequence A}
\]

- **e.g.** TIA: Mild signs and symptoms that resolve without intervention
Methods: Assessment of Value

Reductions in probability for different levels of severity of different consequences are multiplied by the appropriate descriptive parameters to obtain a value. The values are summed to obtain a total value. This process can be repeated for each DRP identified.

System allows multiple consequences to be selected
Economic Results: Main Value Results

- **PROMISe Assessed Sample**
  - 291 Interventions
  - 1779 Assessments
  - 16 Assessors

- **PROMISe intervention data**
  - 2373 Interventions
  - 420,152 scripts

- **Clinical Assessment Process**

- **Average Value of Interventions in PROMISe data**
  - 0.22 days in hospital
  - 1.23 consultations
  - $290 in total costs
  - 44 days of poor health

- **Value of interventions in all Australian pharmacies**
  - 232M scripts pa
  - 1.6M interventions
  - 262,424 days in hospital
  - 1.48M consultations
  - $349M in total costs
  - 53M days of poor health
Conclusions

• Clinical Interventions occur in community pharmacies in Australia at a frequency above 1 in 200 prescriptions
• Common types of interventions relate to drug selection, dose problems and education
• Drugs commonly involved in interventions are antidiabetic agents, drugs for COPD and anti-inflammatory agents
• The value of these activities is estimated at ~$1M per day, at the current level of interventions
Future Work

- PROMISe III
  - Grant received (>3M) for ~200 pharmacy study, across multiple states (trial phase planned for mid 2009)
  - Techniques to increase intervention frequency being tested
  - National rollout intended in 2011, depending on results(!)
    - ~5000 pharmacies

www.promise.org.au