Unused and Expired Medicines (UEMs): A Public Health Challenge

Presenter:
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Community Medical Foundation for Patient Safety
www.communityofcompetence.com
Community Medical Foundation for Patient Safety

- Established in 2003, registered in Texas 2004
- Philosophy based on leadership and the Community of Competence™ (Com.Com)
- A leader in research and educational programs on patient safety and healthcare quality
- Goals strongly support humanistic, patient-centered healthcare system and inclusion of the patients and families in all aspects of healthcare
Community Medical Foundation for Patient Safety--Highlights

- Recognized by U.S. DHHS as Patient Safety Organization #29 (2008)
- Recognized by U.S. EPA (part of funding requirements for drug take back, 2009)
- UEM Project presented at U.S Congressional hearings (2009)
- UEM Project under consideration for the Texas Environmental Excellence Award (2009)
- Faculty members of the National Patient Safety Foundation, Sigma Xi, American Society for Quality Health Care Division
Com.Com as Research Framework for the Unused & Expired Medicines (UEM) Project

- Use framework and methods of Com.Com empirically
- Develop, implement, and evaluate models to safely and legally collect and destroy consumers’ UEMs from homes
- Develop data repository to systematically characterize and report regional and national trends
- Expand UEM project into a national system
Timeline and Benchmarks for UEM Project

- **2002**: Maine Benzodiazepine Study Group
- **2003**: LD1826 (ME) enabling house bill, drug take-back
- **2004**: The National Unused and Expired Medicines Registry
- **2006**: LD411 (ME) secured funds for drug take-back
- **2007**: The Athens Declaration
  - First federal guidelines for consumer drug disposal
  - Annual Survey of Drug Take-Back Programs launched
- **2008**: The National Directory of Drug Take-Back Programs
- **2009**: The Istanbul Declaration (final review)
  - Maine’s 15-day limitation on first prescription
  - Second federal guidelines for consumer drug disposal
  - Maine Declaration (first draft)
Impact on Public Health: Childhood Accidental Poisoning and Overdoses

Almost 40% of accidental poisoning occurs in grandparents’ homes

Source: Minnesota Poison Control, 2004
Impact on Public Health: Accumulation of Drugs by the Elderly

Medication errors and overdoses can occur among seniors

Source: CMFPS 2008
Impact on All Sectors of Society: Contamination of Physical Environment

80% of streams and waterways have traces of pharmaceuticals
Source: US Geological Survey, 2002

Traces of pharmaceuticals found in drinking water of at least 46 million Americans
Source: Associated Press, 2008
Impact on Public Health: Household Drug Theft and Pharming

Prescription drug arrest is 39% of all arrests; between 2003 and 2008, 250% increase in prescription drug arrests

Source: Maine Drug Enforcement Agency (2008)
Impact on Public Health: 
Waste in the Healthcare Systems

Most unwanted medicines are usually flushed down the sink or toilet, but drug take-back programs are now available to intercept these wasted meds.

Source: CMFPS 2008

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Impact on Public Health: Improper International Drug Donation

600 tons of expired, damaged, or inappropriate medicines were donated post-tsunami, 2004

Source: PSF-CI 2005
Framing the Public Health Challenge

Determining the Magnitude

- US pop accounts for 5% of world’s pop
- Global production of pharmaceutical products annually is $600 billion (US)$\textsuperscript{11}
- US consumption of these products is 50% or about $300 billion (US) worth of drugs\textsuperscript{11}
- US consumption growth rate is fastest compared to those of other countries due to more demand (aging population, more prescription, etc.)
Symptoms and Signs

Environmental Impact

Adverse effects on aquatic life
- Continual exposure
- Multi-generational exposures
- High conc in untreated water
- Possible low dose effects

Examples
- Salmon—1 ppb to diazinon disrupts olfactory reception
- Calcium-channel blockers inhibit sperm activity
- Flathead minnow—5 ppt of 17α-ethinylestradiol, feminiz.
- Anti-epileptics are potential human neuroteratogens
Symptoms and Signs

Example of Developmental Defect

Fungicide carbendazim interferes with cellular differentiation at the earliest stage. 90% cent of fish larvae spawned at the hatchery from brood stock taken from the Noosa River (Australia) had two heads.
Symptoms and Signs

Example of Developmental Defect

Ambient exposure to EE2 causes male flathead minnows to develop feminine characteristics (e.g. formation of ovipositor on the ventral side).
Symptoms and Signs

Example of Developmental Defect

Developmental delay caused by exposure to Prozac. Control (left) shows normal growth; treated specimen (right) failed to develop limbs after 57 days.
NSAID diclofenac found in carcasses and eaten by vultures causes poisoning, renal failure, and death. Vulture population has declined by 95%-97%; 2-3 species in South Asia are near extinction.
1.7 million people die from tuberculosis globally each year. A new mutant form XDR-TB, which is immune to all current drugs, has been seen worldwide, including the US, Eastern Europe and Africa.
Generalized Model Based on Community of Competence™ for UEM Project

- Environmental Protection
- Patients/Consumers
- Drug/Law Enforcement
- Medical Practice
- Public Safety and Policy
- Consumer Protection
- Academia and Research
- Patient Safety
- Others
The National Unused & Expired Medicines Registry

- The central component of the *Get Rid of Unused Pharmaceuticals* (GROUP) Campaign
- Classification and coding protocol based on existing systems:
  - Therapeutic class: DAWN (SAMHSA, DHHS)
  - Drug characteristics: FDA NDC Directory
  - Cost (AWP): Red Book
  - Environmental risk/hazard class: JANUS Info
  - Demographic profile: US Census 2000 (zip code)
  - Occupational exposure hazard: OSHA
Status of National Registry

- More than 36 datasets received (varying sizes)
- More than 24,000 entries (UEMs)
- More than 1.7 million pills, tablets, capsules counted
- Leading categories:
  - CNS agents
  - Psychotherapeutic agents
  - Cardiovascular agents
  - Respiratory agents
  - Gastrointestinal agents
  - Alternative medicines
Data Collection
Models of Take-Back Programs
A Model of Mail-Back Program
Drug Take-Back Programs
(n = 79)
Method of UEM Collection
(n = 96)

- Drop-off at event: 30 (31%)
- Drop-off at pharmacy: 39 (41%)
- Direct mail-in: 3 (3%)
- Drop-off at police station: 14 (15%)
- Other: 10 (10%)
UEM Collection Schedule
(n = 82)

- Ongoing: 58 (71%)
- One time: 2 (3%)
- Other: 11 (13%)
- Yearly: 6 (7%)
- Quarterly: 1 (1%)
- Monthly: 4 (5%)
UEM Destruction Method

(n = 70)

- Incinerate: 64 (92%)
- Landfill: 3 (4%)
- Both incin. & landfill: 2 (3%)
- Don’t know: 1 (1%)
- Other: 0 (0%)
Law Enforcement Involvement
(n = 79)

- Yes: 32 (41%)
- No: 47 (59%)
Classification of UEM
(n = 90)

- Medical waste: 7 (8%)
- Hazardous household waste: 38 (42%)
- Nonhazard household waste: 12 (13%)
- Solid waste: 4 (4%)
- Don’t know: 24 (27%)
- Other: 5 (6%)
Purpose of Take-Back Program (n = 326)

- Home safety: 60 (18%)
- Environ protection: 77 (24%)
- Community service: 68 (21%)
- Public safety: 51 (16%)
- Other: 4 (1%)
- Crime prevention: 22 (7%)
- Patient safety: 44 (13%)
Participation in the UEM Registry
(n = 79)

- Yes: 30 (38%)
- No: 26 (33%)
- Don't know or Undecided: 23 (29%)

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Issues of Non-Adherence

• Ref: Variable = REASON; Item 7; Data field 29
• Common Reasons:
  — Medicine expired or outdated*
  — Doctor discontinued medicine
  — Doctor ordered new medicine
  — Patient “felt” better*
  — Side effects or allergic reaction*
  — Patient died or moved away
  — Patient did not want to take medicine*
  — Don’t know or other*
Issues of Non-Adherence

What we are learning from the Registry:

- Patients/consumers often self-medicate
- They are willing to share their reasons for UEMs
- They generally are doubtful of benefits of meds
- They associate new symptoms with new medicines
- They have low threshold in deciding when to discontinue medicine
- They seldom communicate concerns about meds with doctors or pharmacists
- They stockpile discontinued meds
- Take-back programs as an intervention (?)
Issues of Non-Adherence: Postmarket Study

Summary of Postmarketing Study Commitments

- Ongoing: 19%
- Delayed: 2%
- Submitted: 14%
- Terminated: 0%
- Pending: 65%

## Issues of Non-Adherence: Patient/consumer Behavior

<table>
<thead>
<tr>
<th>Reason</th>
<th>Freq</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expired or outdated*</td>
<td>6144</td>
<td>(53)</td>
</tr>
<tr>
<td>Didn’t want to take it*</td>
<td>2357</td>
<td>(20)</td>
</tr>
<tr>
<td>Patient died</td>
<td>1693</td>
<td>(14)</td>
</tr>
<tr>
<td>Don’t know or other*</td>
<td>836</td>
<td>(7)</td>
</tr>
<tr>
<td>Doctor discontinued it</td>
<td>375</td>
<td>(3)</td>
</tr>
<tr>
<td>Patient felt better*</td>
<td>103</td>
<td>(1)</td>
</tr>
<tr>
<td>Doc ordered new meds</td>
<td>92</td>
<td>(1)</td>
</tr>
<tr>
<td>Side effects or interactions*</td>
<td>84</td>
<td>(1)</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td><strong>11684</strong></td>
<td><strong>(100)</strong></td>
</tr>
<tr>
<td><strong>Total due to non-adherence</strong></td>
<td><strong>9521</strong></td>
<td><strong>(81)</strong></td>
</tr>
</tbody>
</table>

Source: Northern California, 2007-2008, Teleosis Institute
# Issues of Non-Adherence: Patient/consumer’s Report of Side Effects

<table>
<thead>
<tr>
<th>UEM</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMBIEN</td>
<td>“became suicidal”</td>
</tr>
<tr>
<td>METHYLPREDNISOLONE</td>
<td>“depression”</td>
</tr>
<tr>
<td>AMOXICILLIN</td>
<td>“pill from hell”</td>
</tr>
<tr>
<td>GABAPETIN</td>
<td>“anxiety”</td>
</tr>
<tr>
<td>GABAPETIN</td>
<td>“made me too drowzy”</td>
</tr>
<tr>
<td>WELCOL</td>
<td>“severe muscle pain”</td>
</tr>
<tr>
<td>ASTELIN</td>
<td>“did not work”</td>
</tr>
<tr>
<td>ASTELIN</td>
<td>“severe fatigue”</td>
</tr>
<tr>
<td>LIPITOR, LISINOPRIL</td>
<td>“jitteriness”</td>
</tr>
<tr>
<td>GLUCOSAMINE</td>
<td></td>
</tr>
</tbody>
</table>

Total = 81 (1%)  

Source: Northern California, 2007-2008, Teleosis Institute
Conclusions

- UEMs are a significant, complex problem
- Evidence is still weak concerning effects on human
- Evidence is strong in environmental impact studies
- The National Registry could be used as a public health surveillance system
- The National Registry could support a regional or a national drug take-back system
- The National Registry could become an international system for cross-national comparison and evaluation of programs
US pop accounts for 5% of world’s pop

Global production of pharmaceutical products annually is $600 billion

US consumption of these products is 50% or about $300 billion worth of drugs

US consumption growth rate is fastest compared to those of other countries due to more demand (aging population, more prescription, etc.)

Imagine waste proportion of 40-50% (from our samples. Are we wasting $150 billion by throwing our meds away?

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Thank you!

For more information, contact

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