Pharmaceuticals in the Environment: How Pharmacists Can Make a Difference

Saturday, February 1, 2014

Conference Slides
Program Schedule

Pharmaceuticals in the Environment: How Pharmacists Can Make a Difference

February 1, 2014

7:30 AM   Check-in

8:00 AM   Welcome
Joe Schieffelin, Solid and Hazardous Waste Program Manager, CDPHE

8:15 AM   Overview: How Do Pharmaceuticals Enter the Environment?
Barbara Bennett, Surface Water Assessor, Colorado Water Quality Control Division, CDPHE; Chair, CREEC

8:50 AM   What Are the Effects of Pharmaceuticals in Aquatic Ecosystems?
Larry Barber, PhD, Research Geochemist, US Geological Survey

9:30 AM   Refreshment Break

9:45 AM   Proper Disposal of Waste Pharmaceuticals from Homes and Health Care Facilities
Greg Fabisiak, Environmental Integration Coordinator, Division of Environmental Health & Sustainability, CDPHE
Kathryn Stewart, Compliance Assurance Unit Leader, Materials Waste Management Division, CDPHE

10:15 AM  Pharmacists Making a Difference: A Pharmacy Medication Take-back Program
Stuart Read, RPh, Director, Pharmacy Services, Vail Valley Medical Center

10:30 AM  Pharmacists Making a Difference: Donated Medications
Frieda Martin, RPh, Pharmacy Manager, TLC Pharmacy

10:45 AM  Introduction to Breakout Groups: Proper Disposal and Prescribing for Less Waste
Rob Valuck, RPh, PhD, Professor, Skaggs School of Pharmacy; Coordinating Center Director, Colorado Consortium for Prescription Drug Abuse Prevention

(Continued on next page)
11:00 AM  **Breakout Group #1: Hospital Pharmacies**  
Facilitators:  
Sunny Linnebur, PharmD, Associate Professor, Skaggs School of Pharmacy  
Lucas Smith, Pharmacy Student, Skaggs School of Pharmacy

11:00 AM  **Breakout Group #2: Retail Pharmacies**  
Facilitators:  
Gina Moore, PharmD, MBA, Director of Clinical Affairs and Associate Professor, Skaggs School of Pharmacy  
Cody Taylor, Pharmacy Student, Skaggs School of Pharmacy

11:00 AM  **Breakout Group #3: Consulting Pharmacies and Other Types of Pharmacies**  
Facilitators:  
Ellen Balkema, RPh, Consultant Pharmacist, PharMerica  
Nicole Dimaano, Pharmacy Student, Skaggs School of Pharmacy

12:00 PM  **Summaries**  
Facilitators

12:30 PM  **Adjourn**
Learning Outcomes

At the conclusion of this activity, the participants will be able to:

1. Describe the mechanisms by which drugs enter the water cycle and occur as trace contaminants in rivers, lakes and groundwater.
2. Describe how pharmaceuticals can cause changes in an ecosystem and cite examples of the effects of specific drugs on fish and other aquatic life.
3. Given examples of particular pharmacy workplace settings, determine if current innovative drug dispensing and take-back practices could be applied.
4. With the help of other participants, create new strategies by which pharmacists can reduce the amounts of drugs that are wasted or that enter the environment.
Faculty

Conference Coordinators

Barbara Bennett
Surface Water Assessor
Colorado Water Quality Control Division
Colorado Department of Public Health and Environment,
Chair
Consortium for Research and Education on Emerging Contaminants

Lillian Gonzalez
Unit Manager
Permits Section, Water Quality Control Division
Colorado Department of Public Health and Environment

Kathleen McCartney, PharmD
Coordinator, Continuing Pharmacy Education
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

Benton Westergaard
Program Administrator, Continuing Pharmacy Education
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

Moderators & Presenters

Ellen Balkema, RPh
Consultant Pharmacist
PharMerica

Larry Barber, PhD
US Geological Survey

Barbara Bennett
Surface Water Assessor
Water Quality Control Division
Colorado Department of Public Health and Environment

Greg Fabisiak
Coordinator, Environmental Integration, Division of Environmental Health & Sustainability
Colorado Department of Public Health and Environment

Sunny Linnebur, PharmD
Associate Professor, Department of Clinical Pharmacy
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

(Continued on next page)
Moderators & Presenters – continued

Frieda Martin, RPh  
Manager, Co-founder  
TLC Pharmacy

Gina Moore, PharmD, MBA  
Director of Clinical Affairs and Assistant Professor, Department of Clinical Pharmacy  
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

Stu Read, RPh  
Director, Pharmacy Services  
Vail Valley Medical Center

Joe Schieffelin  
Manager  
Solid and Hazardous Waste Program  
Colorado Department of Public Health and Environment

Lucas Smith  
Student  
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

Kathryn Stewart  
Unit Leader – Compliance Assurance Unit, Hazardous Materials Waste Management Division  
Colorado Department of Public Health and Environment

Cody Taylor  
Student  
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences

Robert Valuck, RPh, PhD  
Professor, Department of Clinical Pharmacy  
University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences
Welcome

Joe Schieffelin
Solid and Hazardous Waste Program Manager,
Colorado Department of Public Health and Environment (CDPHE)
Pharmaceuticals in the Environment:
How Pharmacists Can Make a Difference!

February 1, 2014

Waste Management Hierarchy

Prevention
  if you can't prevent, then...
Prepare for reuse
  if you can't prepare for reuse, then...
Recycle
  if you can't recycle, then...
Recover other value (e.g. energy)
  if you can't recover value, then...
Disposal
  landfill if no alternative available.
Today’s Agenda

What are the effects of pharmaceuticals in the environment?

How do pharmaceuticals enter the environment?

Proper disposal of pharmaceuticals

Prevent/reduce
Re-use
Recover

Other options:
- Prescribing less
- Re-use/Donations
- Take-back programs
- Other ideas?
Overview: How Do Pharmaceuticals Enter the Environment?

Barbara Bennett
Surface Water Assessor,
Colorado Water Quality Control Division,
Colorado Department of Public Health and Environment (CDPHE);
Chair,
Consortium for Research and Education on Emerging Contaminants (CREEC)
Introduction to Pharmaceuticals as Emerging Contaminants: Where do we find pharmaceuticals in the environment and how do they get there?

Barbara Bennett
Colorado Department of Public Health and Environment

Disclosure Statement

Barbara Bennett
I have no relevant financial relationships with commercial interests pertaining to the content presented in this program.

Overview

- Where do we find pharmaceuticals in the environment?
- Which pharmaceuticals are most commonly found?
- How do pharmaceuticals enter the water cycle?
- How are pharmaceuticals different than other types of pollutants?
- What is known about the risk to human health and the environment?

Where do we find pharmaceuticals in the environment?

- Pharmaceuticals have been detected in lakes and rivers throughout the U.S.
- The highest concentrations of pharmaceuticals are generally detected in waters that receive discharges from wastewater treatment plants.
- Pharmaceuticals, particularly antibiotics, are also detected in waters that receive discharges from concentrated animal feed lots.
- Pharmaceuticals have also been detected in shallow groundwater near septic tanks and other sources of domestic wastewater effluent.

Where do we find pharmaceuticals in the environment?

Pharmaceuticals are also detected in the environment in surprising locations, including:

- Rocky Mountain National Park
- Far out in the open waters of Lake Michigan

Pharmaceuticals in Drinking Water

The Associated Press - March 9, 2008

Pharmaceuticals in finished drinking water in 24 metro areas

Concentrations are in parts per trillion (1 / 1,000,000,000,000)
How do Pharmaceuticals Enter the Water Cycle?

- Pharmaceuticals that are excreted or disposed through flushing enter wastewater collection systems.
- Wastewater treatment plants are not designed to remove pharmaceuticals.
- Removal of pharmaceuticals varies widely depending upon the type of treatment.

Environmental Chemistry of Pharmaceuticals

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Carbamazepine</th>
<th>Acetaminophen</th>
</tr>
</thead>
</table>

Which pharmaceuticals evade treatment most often?

The following pharmaceuticals were found in wastewater effluent from more than 50% of large treatment plants in a recent national study:

- Albuterol
- Atenolol
- Carbamazepine
- Ciprofloxacin
- Diltiazem
- Furosemide
- Gemfibrozil
- Hydrochlorothiazide
- Metoprolol
- Ofloxacin
- Propranolol
- Sulfamethoxazole
- Triamterene
- Tramadol
- Trimethoprim
- Valsartan
- Verapamil


Exposure to Pharmaceuticals Impacts Aquatic Life

- Pharmaceuticals in the environment are generally present in very low concentrations (parts per trillion).
- At these concentrations, pharmaceuticals are not acutely toxic to aquatic life.
- A wide body of scientific studies demonstrate that exposure to pharmaceuticals can cause endocrine disruption, reduced fertility and behavioral changes in aquatic species.
- Pharmaceuticals that are toxic to microbes or algae have the potential to impact fish and wildlife through changes in the food web.
The risk to human health from exposure to trace amounts of pharmaceuticals is unknown.

Concentrations of pharmaceuticals that have been detected in drinking water are orders of magnitude below approved therapeutics doses.

Since hormones are active in the body at extremely low concentrations (parts per trillion), it is possible that some pharmaceuticals may interfere with the human endocrine system, particularly in developing fetuses.

In particular, activated sludge and biological nutrient removal effectively remove hormones and steroids.

Research Needed

Laboratory technology that can measure very low concentrations of pharmaceuticals has only been available for about a decade.

Researchers are making rapid progress on identifying the potential risks to aquatic life.

The risk to human health is generally unknown.

Science emerges much faster than policy.

There are currently no standards or regulations to control or limit discharge of pharmaceuticals.

Water quality monitoring for pharmaceuticals in the U.S. is voluntary.

Quiz Questions

True or False?

Pharmaceuticals are detected in rivers and lakes in concentrations that are acutely toxic to fish.

Antibiotics biodegrade rapidly in the environment.

Even the most advanced wastewater treatment technology available does not remove 100% of pharmaceuticals.

Wastewater plants in the U.S. are not required to monitor or treat pharmaceuticals in wastewater.

Emerging Contaminants

Consortium for Research and Education on Emerging Contaminants

Who participates:
- University researchers
- USGS
- EPA
- Environmental and public health professionals
- Drinking water providers
- Wastewater treatment providers
- Concerned citizens

Sources

What Are the Effects of Pharmaceuticals in Aquatic Ecosystems?

Larry Barber, PhD
Research Geochemist
US Geological Survey
Boulder, CO
Effects of Drugs on Aquatic Organisms

Larry B. Barber  
U.S. Geological Survey  
Boulder, Colorado  USA

University of Colorado  
Skaggs School of Pharmacy  
& Pharmaceutical Sciences

Pharmaceuticals in the Environment:  
How Pharmacists Can Make a Difference?  
February 1, 2014

Disclosure Statement – No Financial Relationships to Disclose

Larry Barber

Statement of Disclosure

I have no relevant financial relationships with commercial interests pertaining to the content presented in this program.
Wastewater Reuse Increasing with Population Growth and Climate Change

Spreading Ponds near Pico Rivera in Los Angeles, California

Widespread occurrence of biologically-active chemicals

The Human Endocrine System

Glands that produce hormones and the corresponding receptors

“govern every aspect of the life of vertebrate animals”

Colborn and others, 1996
**Fish Endocrine Disruption**

*Hypothalamus-Pituitary-Gonadal Axis*

- **Brain**
- **Liver**
- **Pituitary**
- **Testes**
- **Ovary**

**Primary Regulators**
- Temperature
- Day Length
- Water Chemistry
- Social Interaction

**Feedback Disruption**

- **Exogenous Estrogenic Chemicals**

**Differentiation**

- **GnRH** (+)
- **Dopamine** (-)

**Maturation**

- **Liver**
- **Vitellogenin**

**Reproduction**

- **Yolk Protein**

**Androgens**

- Testes

**Estrogens**

- Ovary

**Progestins**

- Androgens
- Estrogens
- Progestins

**Safety Threshold**

- Defined
- No Defined

**Toxicology**

- ppm (mg/L) ➞ Death/Disease

**Endocrinology**

- ppt (ng/L) ➞ Physiology

**USGS**

**ppm** (mg/L) ➞ **Death/Disease**

**Defined Safety Threshold**

**ppt** (ng/L) ➞ **Physiology**

**No Defined Safety Threshold**
What is your favorite pharmacological mode of action?

a) Estrogen receptor binding

b) Selective serotonin reuptake

c) Folate biosynthesis

Mode of Action

Estrogen Receptor (α and β) Binding

Cellular Distributions and Outcomes

- Cardio protection
- Obesity
- Metabolism
- Cancer
- Insulin Regulation
- Diabetes
- Heart/Blood Vessels
- Liver
- Pancreas
- Breast/Prostate
- Gonad
- Brain
- Fertility
- Infertility
- Gonadal Dysgenesis
- Sexual Differentiation/Development
- Neurodegeneration
- Neuronal Remodeling
- Learning Disabilities
- Puberty
- Early Puberty
Estrogen Receptor – Ligand Interactions

17β-Estradiol
Biogenic female sex hormone
155 million women (2007) excrete ~0.1 mg/person/day
= 5,600 kg/yr

17α-Ethinylestradiol (EE2)
Pharmaceutical oral contraceptive
>12 million women (8.1% in 2002)
35 µg/pill x 21 pills/28 d
= 120 kg/yr

Maximum Environmental Concentration
EE2 = 0.8-2.2 ng/L

Country 2007 kg/yr
Belgium 8.0
France 34
Germany 51
Italy 20
Netherlands 15
United Kingdom 26
United States 88


Conjugated (Sulfate Ester) Equine Estrogens
1995 Estrogen Replacement Therapy Use = 1,700 kg/yr

Estrogen Receptor Relative Binding Affinity (%)

<table>
<thead>
<tr>
<th>Estrogen</th>
<th>ERα</th>
<th>ERβ</th>
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<tbody>
<tr>
<td>17β-E2</td>
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</tr>
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<td>17β-EqN</td>
<td>68</td>
<td>90</td>
</tr>
<tr>
<td>Δ⁸ 17β-E2</td>
<td>68</td>
<td>72</td>
</tr>
<tr>
<td>E1</td>
<td>26</td>
<td>52</td>
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<td>Eq</td>
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<td>49</td>
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<tr>
<td>EqN</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Δ⁸ E1</td>
<td>19</td>
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</tr>
<tr>
<td>17α-E2</td>
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</tr>
<tr>
<td>17α-EqN</td>
<td>20</td>
<td>49</td>
</tr>
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Mode of Action – Acute and Chronic Toxicity

Drugs are designed for low toxicity and high potency

EE2 impedes normal reproductive function in humans via ER-mediated MOA

Specific MOA impact is indicated by high acute to chronic ratios (ACR)

Fish EE2 Acute Toxicity:
Lethal Concentration (LC50) = 1.6 mg/L

Fish EE2 Chronic Toxicity:
Reproduction Predicted No Effect Concentration (PNEC) = 0.35 ng/L

Fish EE2 ACR = 4,600,000

Invertebrate EE2 ACRs = 10-570

Hazard Quotient

low-flow

MEC/PNEC = (0.80 ng/L)/(0.35 ng/L) = 2.3

Regulatory MEC Threshold = 1 µg/L


Mode of Action – Extrapolation of Aquatic Effects using Therapeutic Plasma Concentrations

Effects Ratio = HtPC/FssPC

Human therapeutic outcome
Drug administration
Metabolism/Elimination
Exposure
Bioconcentration
Non-target effect

Fish steady-state plasma concentration calculated by partitioning from water

FssPC = P x Environmental Concentration

Log Pssw = 0.73 x log Kow – 0.88

Conservation of enzyme and receptor systems between mammals and fish

Adverse Outcome Pathway

Many assumptions


Can drug concentrations <1 part-per-billion in water have implications for aquatic organisms?

a) Yes  
b) No  
c) Maybe
Female-biased sex ratio
Gonadal intersex
Plasma vitellogenin in males
Decreased sperm quality

ER Mode of Action Adverse Outcome Pathway

Controlled On-Site Exposure Experiments
Effluent/Stream
Male fathead minnows
Continuous flow/28 days
Constant conditions

Rapid de-masculinization
Adverse reproductive outcome

Fathead Minnow Exposure - Summer 2005

The estrogen receptor mode of action is important because:

a) 17β-Estradiol controls vertebrate reproduction

b) Estrogen receptors are located in a variety of tissue types

c) Many disease outcomes are estrogen receptor mediated

d) Estrogenic effects of drugs only impact human targets
Mode of Action – Neuroendocrine System

Selective Serotonin Reuptake Inhibitors

Antidepressants are Widely Prescribed in U.S. (2007)

#3 citalopram CIT
#12 venlafaxine VEN
#21 duloxetine DLX
#57 bupropion BUP
#123, paroxetine PRX
#159 sertraline SER
fluoxetine FLX
fluvoxamine FLV

Function by inhibiting neuronal reuptake of serotonin in mammals

0.03 µg/L FLX induces crustacean and bivalve spawning

Selective Uptake of Antidepressants in Boulder Creek White Sucker Brain Tissue

Downstream from WWTP

SER greatest in brain tissue

VEN greatest in water and sediment

SERwp 3 ng/kg
SERwb 1,500 ng/kg
VENwp 220 ng/kg

Antidepressants in 24 WWTP Impacted Streams

Lee et al. 2011, U.S. Geol. Survey Data Series 575:49.

Do Antidepressants Influence Predator Avoidance Behavior in Larval Fathead Minnows?

12 day exposure

Latency Period (millisecond)
Escape Velocity (body length/ms)

Total Escape Response

 Decrease Predator Avoidance Adverse Outcome Pathway

**Effects Ratios: Sertraline in Fathead Minnows**

**HtPC 190 ng/mL (product registry)**
Use log D (3.77 @ pH 8.5) to calculate \( F_{\text{HtPC}} \)
28 Day exposure of adult (>120 day) males


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**Mode of Action – Folate Synthesis Inhibition**
**By the Antibiotic Sulfamethoxazole (SMX)**

**SMX widespread in surface water and groundwater**

**Environmental:**
Measured concentrations
0.2–5 µg/L

**Clinical:**
Minimum inhibitory concentrations
250–130,000 µg/L

---

Interferes with

**analog to**
\( p \)-aminobenzoic acid (\( p \)-ABA)

**Evolutionary conservative folate biosynthetic pathway**

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**Effects**

**Target**
Toxic to bacteria
Non-Target
Toxic to plants
Sub-Clinical SMX Concentrations Impact Groundwater Microbial Community Function

Detected in 19% of surface waters in National Survey
SMX $C_{\text{max}} = 1.9 \, \mu\text{g/L}$

Cape Cod groundwater contamination plume
SMX $C_{\text{max}} = 1.5 \, \mu\text{g/L}$

SMX Exhibits Herbicidal Activity to Duckweed
(Lemna gibba)

<table>
<thead>
<tr>
<th>End Point</th>
<th>Type</th>
<th>EC50 $\mu\text{g/L}$</th>
<th>HQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frond number</td>
<td>Gross</td>
<td>132</td>
<td>0.01</td>
</tr>
<tr>
<td>Frond weight</td>
<td>Gross</td>
<td>61.6</td>
<td>0.03</td>
</tr>
<tr>
<td>$p$-ABA</td>
<td>MOA</td>
<td>3.36</td>
<td>0.56</td>
</tr>
</tbody>
</table>

Hazard Quotient $MEC = 1.9 \, \mu\text{g/L}$

Mode of Action and Adverse Outcome Pathways Predict SMX Will Impact Non-Target Organism

Folate Biosynthesis Pathway is Conserved Between Plants and Bacteria

List three actions individual pharmacists can implement to minimize impacts of drugs on the aquatic environment.

Thank You

lbbarber@usgs.gov
Proper Disposal of Waste Pharmaceuticals from Homes and Health Care Facilities

Greg Fabisiak
Environmental Integration Coordinator
Division of Environmental Health & Sustainability
Colorado Department of Public Health and Environment

Kathryn Stewart
Compliance Assurance Unit Leader
Hazardous Materials Waste Management Division
Colorado Department of Public Health and Environment
Pharmaceuticals in the Environment: How Pharmacists Can Make a Difference
CU Skaggs School of Pharmacy and Pharmaceutical Sciences
February 1, 2014
Greg Fabisiak and Kathryn Stewart

No relevant financial relationships with commercial interests pertaining to the content presented in this program.

The public wants to know how.

What advice should pharmacists offer?

Methods depend on the type of drug.

Controlled Substances
Non-Controlled Substances

Can pharmacies accept them for disposal?
Perhaps in the future...

- The Controlled Substances Act does not allow for collection by anyone other than law enforcement.
- DEA-proposed rules, if adopted, would allow for collection by approved “authorized collectors” including retail pharmacies (drop boxes and mail-back envelopes).
- DEA rules were published for public comment on 12/21/2013. They are yet to be finalized.

...but at present, the answer is no.

What are current options?
Best Advice: Surrender to law enforcement.

- DEA National Take-Back Initiative
  - Held every spring and fall since October 2010
  - www.dea.gov
- Local take-back events in conjunction with law enforcement activities.
- Police and sheriff office drop-boxes.
**Controlled Pharmaceutical Disposal**

- **What are current options?**
  - Next Best Advice: Trash disposal.
    - Do so carefully to deter diversion or accidental poisoning.

  ![Image of trash can and newspaper]

**Non-Controlled Pharmaceutical Disposal**

- **What are current options?**
  - Next Best Advice: Pharmacy-Based Take-Back Programs
    - Colorado Medication Take-Back Project
      - 11 sites in Metro Denver and Summit County
      - [www.coloradomedtakeback.com](http://www.coloradomedtakeback.com)
    - Dispose My Meds Program
      - 12 sites across Colorado
      - [www.disposemymeds.org](http://www.disposemymeds.org)

**Non-Controlled Pharmaceutical Disposal**

- **What are current options?**
  - Best Advice: Pharmacy-Based Take-Back Programs

**Non-Controlled Pharmaceutical Disposal**

- **What are current options?**
  - Best Advice: Pharmacy-Based Take-Back Programs
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**Non-Controlled Pharmaceutical Disposal**

- **What are current options?**
  - Next Best Advice: Trash disposal.
    - Do so carefully to deter diversion or accidental poisoning.

**Non-Controlled Pharmaceutical Disposal**

- **What are current options?**
  - Can pharmacies accept them for disposal?
    - Yes, but...
      - It should be done as part of a well-planned program.
      - A competent waste contractor should be employed, utilizing:
        - Disposal methods compliant with federal, state, tribal and local laws and regulations
        - Only household medication wastes can be accepted.
        - Qualify for Household Hazardous Waste Exemption

**Non-Controlled Pharmaceutical Disposal**

- **What are current options?**
  - Best Advice: Surrender to law enforcement.
    - (Same as for controlled medications, but law enforcement agencies may have difficulty handling large volumes of non-controlled medications.)
      - DEA National Take-Back Initiative
      - Local take-back events in conjunction with law enforcement activities.
      - Police and sheriff office drop-boxes.

**Current Disposal Options**

- Controlled
  - DEA National Take-Back Initiative
  - Law Enforcement Box/Local Event
  - Trash
- Non-Controlled
  - Pharmacy Drop Box/Mail-Back
Controlled Household Meds

Non-Controlled DEA National Take-Back Initiative

Low Enforcement Box/Local Event

Pharmacy Drug Box/Mail-Back

Trash

Household Pharmaceutical Disposal Resources

- Contact CDPHE
  - 303-692-2903
  - greg.fabisiak@state.co.us

- Colorado Consortium for Rx Drug Abuse Prevention
  - Public awareness and disposal group messaging is coming soon!

Disposal regulations for businesses are much more stringent than for wastes coming from households.

Medication Waste from Businesses

- Nursing homes
- Hospice facilities
- Assisted living facilities
- Clinics
- Hospitals

Household medication take-back programs are not options for businesses.

Best Disposal Options

1. Redistribute if able to be reused.

2. Send waste medications to an authorized incinerator or other authorized disposal facility.
Do not dispose of medication wastes in trash cans or other similar containers, and especially not down drains.

What about controlled substances?

Colorado waste requirements defer to DEA requirements and other efforts to prevent diversion.

Website

- www.colorado.gov/cdphe/medicalwaste
  - Evaluating Wastes in Health Care Settings
  - Examples of Pharmaceuticals
  - Generator Requirements of the Colorado Hazardous Waste Regulations
  - Medical Waste Generator Compliance Bulletin
- www.colorado.gov/cdphe/hm
  - CO Hazardous Waste Regulations 6 CCR 1007–3
  - CO Solid Waste Regulations 6CCR 1007–2 Sec 13

Tip of the Iceberg!

- Contact Us
  - Training
  - Additional information
  - Dan Goetz: 303–692–3341 | daniel.goetz@state.co.us
Pharmacists Making a Difference: A Pharmacy Medication Take-back Program

Stuart Read, RPh
Director, Pharmacy Services
Vail Valley Medical Center
Vail, CO
DEVELOPING A MEDICATION “TAKE BACK PROGRAM” IN AN OUTPATIENT SETTING

Stu Read, RPh
Director, Pharmacy Services
Vail Valley Medical Center
Vail, Co

HOW WE FOUND OUT ABOUT THE PROGRAM

We implemented this program in August, 2009

Read about “Take Back Programs” in NCPA journal and used resources mentioned and the necessary steps outlined to get program up and running

STEPS TAKEN

1. Contacted regulatory agencies to determine any laws and regulations that would impact the program
   (contact info later slide)
   - Colorado State Board of Pharmacy
   - DEA
2. Contacted our reverse distributor to discuss whether or not they would be able to dispose of the medications we would receive in this program. They could not—not licensed to transport & dispose of pharmaceutical waste.
3. The hospital was working with Clean Harbors (SteriCycle another vendor out there) as their waste disposal partner so we became part of that. All of the “Take Back” meds are household hazardous waste (HHW) except inhalers which are handled separately
4. Held a meeting with local law enforcement (both county and city), Eagle County HHW department and Eagle River Water & Sanitation. All were very excited and offered any and all help in getting this off the ground.
5. Handling of controlled meds a challenge at that time—DEA protocol that is no longer in effect (see handout for old protocol).
   Current DEA info: “There are regulations being drafted in Washington DC which are not yet in effect. Until such time as they are unveiled and finalized, the only entities authorized to receive “end user” controlled substances are sites manned by law enforcement and the bi-annual DEA National Take Back Initiative”.
6. Spoke with other pharmacies that were listed in the journal
7. Decided what items we were willing to accept
8. Developed an implementation plan and P&P’s (see handout)
9. Which receptacle we wanted to use (DVault—info to follow)
10. Training of staff
11. Marketing
   - Newspaper ads (see handout)
   - Bag stuffers (see handout)
   - Newspaper article
   - Info on website
KNOWLEDGE QUESTIONS

Which of the following would you contact as possible partners in establishing your take back program?

a. County sheriff  
b. Local police dept.  
c. Water treatment facility  
d. All of the above

Which of the following is an obstacle in establishing your take back program?

a. State Board of Pharmacy  
b. DEA  
c. Local law enforcement  
d. None of the above

NEW RESOURCE

NCPA developed a new program: "Dispose My Meds™

New "TakeAway Environmental Return System™—see hand out

Contact info on later slide

VOLUME

We gather about 7.5–10 gallons/month per pharmacy unless we do a special marketing promotion (Health Fair, Nat’l Take Back Day)

COSTS

Disposal bin: approx. $650

Labor to get program set up: ??

Marketing—flyers, newspaper, radio, TV etc: ??

(we have run co-op ads with our partners in this – Eagle Water & Eagle County HHW)

Cost per 5 gallon pick up: $45 plus transport fees

CONTACT INFO

Stu Read: read@vvmc.com
Eagle Valley Pharmacy, 970–479–7253
www.vvmc.com/pharmacy

Colorado State Board of Pharmacy:
http://www.dora.state.co.us/pharmacy/

http://dvault.com/

CONTACT INFO (CONT’D)

TakeAway Environmental Return System:

Clean Harbors: 303.371.1100 (Denver office)

http://www.cleanharbors.com

National Community Pharmacists Association (NCPA)

http://www.ncpanet.org/pdf/pdp/Online-Ordering-Instructions-for-NCPA-Members.pdf

800–544–7447
Safe Drug Disposal Program

3 locations to Drop Off Unwanted Medications

- Eagle Valley Pharmacy – located in Vail Valley Medical Center, Vail
- Edwards Medical Center Pharmacy – located in Shaw Pavilion, Edwards
- Household Hazardous Waste Facility – located at the Eagle County Landfill, Wolcott

Leave items in original containers. Mark out any personal information if you wish.

Bring items to Eagle Valley Pharmacy, Edwards Medical Center Pharmacy or Eagle County Household Hazardous Waste Facility. Show container to staff member to make sure item is acceptable for disposal. Deposit into medication disposal unit. Pharmacy staff can determine if an item is “controlled”, which cannot be collected without law enforcement.

For more information call either 970-569-7676 (Edwards) or 970-479-7253 (Eagle Valley)

**Items Accepted**

- ✔ Prescription medications
- ✔ Over-the-counter medications
- ✔ Medical Samples
- ✔ Medications for pets
- ✔ Vitamins
- ✔ Medicated ointments/lotions
- ✔ Inhalers
- ✔ Liquid medication in glass or leakproof containers

**Items not accepted**

- ✔ Needles (sharps)
- ✔ Thermometers
- ✔ Controlled substances (narcotics) such as-
  - Vicodin, percocet, Oxycontin, codeine
  - containing cough syrups, Tylenol with Codeine*
- ✔ IV bags
- ✔ Bloody or infectious waste
- ✔ Personal care products
- ✔ Business waste
- ✔ Empty containers
- ✔ Hydrogen peroxide
- ✔ Aerosol cans

*Controlled substances can only be collected when law enforcement officials are present. The Safe Drug Disposal Program partnership will periodically arrange collection events with a law enforcement presence to allow for the safe disposal of controlled prescription drugs. The partnership is working to create a collection location available to the public on an ongoing basis.

The Eagle County Sheriff’s Office, Vail Police Department, Eagle County Household Hazardous Waste Facility and Eagle River Water & Sanitation District are partnering with the VVMC towards the objective of safe disposal of prescription and non-prescription drugs. This will help to keep kids, juveniles and adults safe from intentional misuse of medicines, or accidental poisoning. It reduces the amount of drugs in wastewater and helps to protect our watershed.
Secure Collection Unit

Model Number DVCS0023

Standard Features

- Galvannealed-steel depository, collection and storage unit
- Security-Drop Door - US Pat. 6,347,737
- Deposit operation - simply open, drop and go
- Front key-locked access doors allow units to be installed against walls
- Removable totes for easy collection
- Stainless steel hinges
- Weather resistant
- Constructed of heavy-duty, 16 gauge steel
- Durable powder coated poly-hammer finish
- Colors: Black, White, Green and Gray
- Electrical knock-outs for underground feeds

Optional Features - Call for Details

- Push-button locks for access doors
- Rear access door configuration
- Totes with secure lids (nestable & stackable)
- Pedestal unit
- Custom colors
- Also available in aluminum
- 3-point locking systems
- *Patented Information Systems

Weight and Dimensions

- Weight - 90 lbs.
- Overall Dimensions 19"W x 40"H x 19"D

Shown with front key-locked access-door open (left) and close-up of tote (right).
Floor Express Low Tech Kiosk - Deluxe Hopper Door, DVSC0024
Pharm or Sharps Collection

Our Price: $669.00
Sale Price: $620.47

Product Code: DVSC0024-SLD-4

Choose your options...

- Deposit Door Option:
  - Deposit Door Self Close Assembly [Add $95.00]
  - View Port For Access Door [Add $12.50]

- Hardware Kit Option:
  - Installation Hardware Kit - Secures Units to Floors, Walls or Both [Add $19.95]

- Door Lock Options:
  - Dual Posi-Lock Key Option [Add $25.00]
  - Dual Pad-Lock Option - Pad-Locks available separately [Add $35.00]
  - Single Posi-Lock Key Option - Included As Standard

Supplies:
- Supply Starter Pack [Add $56.61]
  - 12, 14 X 14 X 14 Corrugated Boxes
  - 1, Tape Gun & Tape 2-Pack
- Supply Pack 1 [Add $113.22]
  - 24, 14 X 14 X 14 Corrugated Boxes
  - 1, Tape Gun & Tape 2-Pack

choose a color
- Color: Red Semi-Gloss Polyhammer Tone Powder Coat

Qty: 1
Add to cart

Description
Floor Mount Model Number DVSC0024-SLD-4
Suitable for Pharm or Sharps Collection Solutions
Full Front Single Key-Locked Door
Overall Dimensions 22"W x 39.000"H x 20"C
Weights 165 lbs.
Fully Assembled
Shipping via Motor Freight in 24-48 hours

Features
- Deposit operation - "open, drop and go"
- Deluxe Key-locked chute door prevents after hours deposits
PROPER MEDICATION DISPOSAL
UTILIZING THE “TAKE BACK” PROGRAM
OF EDWARDS PHARMACY & EV PHARMACY
(newspaper article)

In August of 2009 the 2 pharmacies developed and implemented a “medication take program” to facilitate proper disposal of unwanted medications that may be around the house. This program was developed with input and ideas and complete collaboration of the Eagle County Sanitation District Household Hazardous Waste (HHW), Eagle County Water, Eagle County Sheriffs Dept & the Town of Vail PD.

Why is this needed?
In the US, an estimated 250 million pounds of unused medications are improperly disposed of each year. The adverse effects of that improper disposal include:

- Environmental Impact--A 2008 Associated Press Investigation discovered a wide array of pharmaceuticals detected in the drinking water supplies of 24 major metropolitan areas affecting, at least 41 million Americans

- Accidental Ingestion by children, elderly, and pets

- Prescription Medication Abuse--The Partnership for A Drug-Free America reports that every day there are 2,500 teenagers using a prescription medication to get high for the first time. With the exception of marijuana, teens are abusing prescription medications more than any illicit drug. These medications, if unused and just lying around the house, should be disposed of properly.

- The Office of National Drug Control has found that prescription drugs are the drug of choice among 12- and 13-year olds, while a third of all new abusers of prescription drugs were between the ages of 12 and 17.
Though it may be argued that the presence of drugs in drinking water is negligible, more and more consumers are disposing of unused medicines by flushing them down the drain, adding pharmaceutical pollution to our waters. In addition, medicines thrown in the trash can end up in landfills if not first picked up by children, pets, sanitation employees, or anyone who rummages through trash.

- The U.S. Geological survey’s 2002 report showed that 80 percent of surface water samples taken nationwide contained one or more pharmaceutical or personal care compounds.
- The problem of unused prescription medication in households contributes to the more than 20,000 unintentional poisonings annually in the U.S.

How to drop off meds & what to drop off

*See attached*

Patients of any pharmacy are invited to safely dispose of unused and expired medications (RX & OTC) free of charge by bringing in the drugs in their original stock containers and placing them in the “take back bins” at both the Edwards Medical Center Pharmacy & the Eagle Valley Pharmacy during normal hours of operation. Please Call _________________ for details.

For controlled substances (unwanted/expired) pain meds, sleeping pills, cough syrups,) the Drug Enforcement Agency (DEA) has instituted National Take back days during the year where these meds may be returned to participating law enforcement offices to be disposed of properly. This coming Oct 29th is one of these days. Vail PD and Eagle County sheriff are participating in this day. See newspaper ads for times & locations.

How are these meds dropped of at the pharmacies safely disposed of?

These 2 pharmacies are owned and operated by Vail Valley Medical Center. VVMC is contracted with “Clean Harbors Environmental Services, Inc.”. This is a federally licensed hazardous waste disposal company and picks up once a month from the different VVMC facilities.
TAKE BACK PROCESS

1. People bring in their meds
2. Pharmacy staff member MUST look at what they bring in
3. If non-controlled, have patient mark out their info on bottle and drop in bin
4. If controlled substance, they must keep and be told to take to Vail PD or Eagle Cty Sheriff for disposal or must retain until another collection event with law enforcement present or the National Take Back Day
5. When container ¼ full, remove bag & replace. Call facilities to provide container for Clean Harbors. Facilities will store the container for Clean Harbor pick up.
6. Safe Harbors will be picking up on a routine basis. Frequency will be determined.
What to do:

1. Gather your unwanted medications and other approved items (see list).
2. Leave items in original containers. Mark out any personal information if you wish.

Drop Off Unwanted Medications Here

YES: Items Accepted

- Prescription medications
- Over-the-counter medications
- Vitamins
- Medications for pets
- Medical samples
- Inhalers
- Liquid medication in glass or leakproof containers
- Medicated ointments/lotions
- Controlled substances (narcotics)

NO: Items Not Accepted

- Aerosol cans
- Hydrogen peroxide
- Empty containers
- Business waste
- Personal care products
- Blood or infectious waste
- IV bags
- Thermometers
- Needles (sharps)
Pharmacists Making a Difference: Donated Medications

Frieda Martin, RPh
Pharmacy Manager,
TLC Pharmacy
Colorado Springs, CO
What are some barriers for access in healthcare, ie: treatment and medication?

What are some challenges in receiving medications that can be re-dispensed?

In Our community we have had Over 80,000 Uninsured Neighbors in any given year!
At the end of 2014 we will still have 12,000 without any insurance (Colorado Health Initiative)
The waiting list to be seen in our local government programs have been up to 17 months long!

The Vision
With So many having no where else to turn, work began on these Ministries in 2003. Members of the Church and the community began to plan, and fund-raise to make these ministries happen. The Clinic began seeing patients in 2005 and the Pharmacy opened its doors in January of 2010.

The Clients
- Uninsured Adults ages 18 through 64
  - Residents of El Paso & Teller county
- Low income
  - Less than 200% of Federal Poverty Guideline
  - (Family of 4 can make no more than $44,100 and still be eligible.)

• The Mission
  Provide Access For Primary Health Care.
  Ensure Safe Access To Medications
  Provide Education
  Promote Preventive Health
  Provide A Caring Environment For uninsured, low-income residents
A Ministry Of Healing & Hope.

- Only free pharmacy in Colorado
- Where caring for others is not only our mission, It’s our passion!
- Established 2010

That’s The Choice Many Of Our Neighbors Have To Make.

TLC Pharmacy
- Only free pharmacy in Colorado
- Where caring for others is not only our mission, It’s our passion!
- Established 2010

Drugs
- Purchased by pharmacy
- Donated by Pharmaceutical companies
- Received from institutions such as nursing homes, licensed facilities, prescription drug outlet
The Need

- In 2012, 2013
  - 19,250 prescriptions dispensed
  - Wholesale value of over 4 million dollars

Colorado Revised Statutes

- Allow the donation of unused Meds from licensed facilities (C.R.S 12-42.5-133)
- Hx–SENATE BILL 10–115
- Board of Pharmacy Rules 3.00.80

Expected Benefits

Medication donations have Safely helped the community
- Our Tax dollars at work within our community
- Pharmaceutical waste reduction in the nursing facilities

An Unexpected Benefit

Drugs supplied by the pharmacy to ex-offenders reduced the state recidivism rate by 40%.

Future

Partnership with Local and State government to increase the donations
- Pilot project with Sirum (Supporting initiative to redistribute unused medicine)