Design Considerations for Packaging, Storage and Disposal Options to Enhance Opioid Safety

Gary Slatko
Associate Director,
Office of Medication Error Prevention and Risk Management
Center for Drug Evaluation and Research
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Overview

• Addressing the Problems
• A Conceptual Design Approach
  I. Analyze Opioid Use Problems for Associated Behaviors
  II. Consider Design Options (Examples)
  III. Validate with End Users
• Design Principles
• Questions
Addressing the Problems of Opioid Use

• Each opioid use problem (accidental exposure, misuse, third party access, excess supply) has an associated set of behaviors

• Attempts have made to deter/manage these problems with different design options
  – Historically, some repurposed from other applications (e.g., adherence systems)
  – More recently, more innovative designs targeting associated behaviors

• A conceptual approach to analyzing, designing and validating design options, including some examples* will be presented

*Examples are for illustration and not an endorsement of any one approach over others

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A Conceptual Design Approach

Analyze → Behaviors → Design → Data → Validate → Data

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Analyze Opioid Use to Identify Associated Behaviors

• Analyzing how the opioid medication use system may fail is a starting point for identifying associate behaviors as possible targets for designing interventions

<table>
<thead>
<tr>
<th>Failure</th>
<th>Associated Behaviors</th>
<th>Possible Option Designs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient does not securely store medication</td>
<td>Patient unaware, patient forgot</td>
<td>Protected storage, tamper evident packaging, tracking</td>
</tr>
<tr>
<td>HCP prescribes excessive amount of medication</td>
<td>HCP unaware, HCP habit</td>
<td>Unit of use blister package with limited supply</td>
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<tr>
<td>Patient retains excess unused medication</td>
<td>Fears delay in future access</td>
<td>Deactivation/disposal system</td>
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• Evidence-based analytical methods (e.g., Failure Mode and Effects Analysis, Probabilistic Risk Assessment) can help the designers of such options...
  – Anticipate how the opioid medication use system may fail
  – Identify the potential causes of these failures
  – Prioritize associated behaviors as targets for applying or designing interventions
Consider Design Options

**Existing Options**
Use, repurpose or enhance existing options

**Novel Options**
Develop new options to prevent/deter, detect/track, or monitor/manage the targeted behavior(s)

**Integrated Approaches**
Redesign, combine and/or integrate options into management programs and/or healthcare systems
- Redesign an existing option
- Combine to concurrently address multiple targeted behaviors
- Integrate options within broader management programs (e.g., REMS) and/or healthcare delivery system programs
- Others

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Existing Options

Use, Repurpose or Enhance Existing Options

- Calendar/blister packaging
- Limited supply packaging (e.g., “Z-pack”)
- Controlled access systems (e.g., locking caps)
- Tamper detecting/resistant packaging (e.g., individual dose package)
- Deactivation/disposal options (e.g., charcoal pouches)
- Medication adherence support systems
Example*: Zithromycin ("Z-Pack")

- Marketed option that limits medication supply, tracks use in blister/calendar packaging, and communicates instructions
- Pros: Lower technology, does not alter patient routines, adds opportunity to include risk messaging or instructions
- Cons: Lacks access controls or features to control rate of consumption

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Example*: Locking Caps

- Marketed option that controls bottle access
- Pros: Lower technology and lesser impact on typical patient routines
  - Opaque bottle conceals contents
- Cons: Does not limit frequency of openings or number of tablets that can be accessed at each opening; may slow intended patient access; could incur out of pocket costs

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Example*: Medication Deactivation Systems

- Marketed options that deactivate or destroy unused medication
- Pros: Lower technology, may be used for multiple dosage forms
- Cons: Requires additional discretionary step(s) that are not routine; could incur out of pocket costs

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Develop new options that target behaviors associated with opioid use problems

• Identify target behavior(s), then design options that prevent/deter, detect/track, +/- or monitor/manage target behavior(s).

• Examples*
  – Bluetooth bottle cap reports openings
  – Ingestible sensor reports pill ingestions
  – Cell module reports blister opening
  – Controlled dispensing manages/tracks consumption rate
  – Others

• Pros: More targeted, more informational
• Cons: More complex, higher technology, more costly, generally less “passive”, may not be available universally

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Example*: Abilify MyCite

- Tablet embedded with ingestible sensor sends signal via wearable patch to smartphone app and web-portal for HCPs and caregivers
- Pros: Intended to confirm ingestions, HCP oversight (with permission), individualized pill tracking numbers
- Cons: Active requirements, high tech, cost, HCP’s time to ensure patient capable/willing to use, does not manage access or consumption, possible skin patch irritation, ingestion detection may be delayed or not occur

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Redesign, combine and/or integrate options within management programs and/or healthcare systems

- **Redesign an existing option** to address identified target behavior(s)
- **Combine redesigned and novel option(s)** for multiple target behaviors e.g.*, 
  - Limited supply/blister pack + ingestion tracking + disposal pouch
- **Integrate above within safety programs and/or delivery systems** e.g.,
  - Within broader medication safety management programs (e.g., targeted education in patient labeling, REMS HCP training)
  - Within other healthcare delivery system programs (e.g., prescription drug monitoring programs, pharmacy medication therapy management (MTM) programs, health plan care management programs)
- Others

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Example*: Lazanda (fentanyl nasal spray)

- Combines **several existing interventions**...
  - Child-resistant container
  - Counter that tracks doses used and remaining
  - Limits total supply to 8 doses per bottle
  - Packaged with a separate disposal pouch

...**within the TIRF REMS** Access program

- HCPs must enroll and review REMS educational materials
- Outpatients must understand risks and benefits and sign a Patient-Prescriber Agreement
- Pharmacies must enroll in the program and agree to comply with the REMS
- Wholesalers and distributors must enroll and distribute only to authorized pharmacies.

- Does not control rate of dosing and vulnerable to errors in use (e.g., forgetting to re-store the spray bottle)

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A Conceptual Design Approach

Analyze → Behaviors → Design → Validate

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End-User Validation

• Validate safe and effective use, acceptance and usability by end users
  – Confirm that the option(s) target the problem(s) and associated behavior(s)
  – Demonstrate option(s) address patient needs
    • Patients find acceptable and willing to use
    • Patients able to comprehend how to use
    • Patients can demonstrate that they can use
    • Design considers patients’ preferences
  – Culmination of testing done iteratively during the design process
  – Resulting data may support regulatory submission
End-User Validation

• Consider and mitigate potential implementation barriers
  – Passive vs. active systems i.e., reflect existing patterns rather than alter routines
  – Automatic vs. manual
  – Sustainable vs. not sustainable over time
  – Unanticipated consequences
  – Need for redundancy
  – Integration into delivery system: feasibility of distribution, timeliness of availability for legitimate patient use, availability for repeated use, affordability, etc.
4 Design Principles to Consider

1. Use **evidence-based approach** to analyze use problem and identify associated behavior(s) as target(s) for intervention

2. Design with **the end-user in mind**, addressing one or more targeted behaviors, while minimizing foreseeable use errors and implementation barriers

3. Anticipate potential **second order effects** of the option

4. Consider **real-world programs and/or systems** into which design will be used