

Using Adverse Event Data to Improve Drug Labels

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Goals of Medication Labeling

- Maximize Benefit
 - Promote “use as directed”
- Minimize Harm
 - Prevent incorrect use or “misuse”
 - Identify adverse events
 - Mitigate adverse events

Components of Package Insert

- To Maximize Benefit
 - Dosage and administration
 - How drug is supplied
 - Indication?

Components of Package Insert

- To Minimize Harm
 - Contraindications
 - Warnings (Black Boxes)
 - Precautions
 - Interactions
 - Carcinogenesis, mutagenesis, impairment of fertility
 - Teratogenicity (Pregnancy category)
 - Drug abuse and dependence
 - Use in pregnancy and nursing mothers
 - Use in children and older adults
 - Overdosage

Labeling for Safety

- *Form* of safety information
 - Target is the patient / lay caregiver
 - Literacy issues
- *Content* of safety information
 - Scarce “real estate”
 - **Prioritize based on evidence of harm**
 - By frequency of harm?
 - By severity?
 - Personalized / Computerized decision support?

Examples: Evidence & Implications?

- Cough and cold medicines and children
 - Unsupervised ingestions cause 80% of emergency (ED) visits in 2-5 year-olds
 - Label for safe storage?
 - Caregiver overdosing often identified in cases of infant deaths
 - Label for dosing and interactions?
 - Allergic reactions relatively rare

Examples: Evidence & Implications?

- Antibiotics
 - 79% of ED visits for allergic reactions¹
- Older Adults
 - Insulin, warfarin, digoxin cause 33% of all ED visits for adverse drug events²
 - Hypoglycemia caused 95% of insulin visits
 - Label for recognition of signs of hypoglycemia?
 - Bleeding caused 73% of warfarin visits
 - Label to encourage monitoring?