Communicating Drug Safety Information

Joyce H.S. You, PharmD, BCPS (Infectious Diseases)
Associate Professor, School of Pharmacy
The Chinese University of Hong Kong
Outline

- Evolution of Drug Safety Communication
- Pros and Cons of Drug Safety Communication
- Challenges of Risk Communication
Drug Safety Communication - Evolution

• 1500s, Royal College of Physicians stated:
  • “Let no physician teach the people about medicines or even tell them the names of the medicines, particularly the more potent ones...for the people may be harmed by their improper use.”
  • Physicians who violated this principles were fined 40 shillings.
Drug Safety Communication - Evolution

• 1938, the US Food and Drug Administration (FDA) stated:
  • Drug labels “should be written ‘only in such medical terms as are not likely to be understood by the ordinary individual’.”
Drug Safety Communication - Evolution

- 1990s, FDA’s role of drug information communication has evolved:
  - Professional label (targeted at healthcare providers)
  - Plus two forms of regulated consumer information
    - Medication Guide
    - Patient package insert
Drug Safety Communication - Evolution

- Medication Guide
  - A pharmacy handout that comes with the prescription medicine
  - Information directed to the patient could prevent **serious adverse events** or affect a patient’s decision to use, or continue to use, a product, or when adherence to directions is crucial to a drug’s effectiveness
Drug Safety Communication - Evolution

- Patient Package Insert
  - included in the manufacturer’s packaging.
  - inform the patient about the nature of the drug, its proper use, and warnings and side effects.
  - [http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020753s007PatientInfo.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/020753s007PatientInfo.pdf)
Drug Safety Communication - Evolution

- 2006, FDA modified drug label format:
  - Make it useful and accessible to the consumer.
  - A “Highlights” section is added to summarize key prescribing information, including key points to be discusses with patients.
Pros and Cons of Drug Safety Communication

- Reason (1) The public wants to know about drug safety and drug risks
- Pros: Transparency fosters greater trust
- Cons: Risk information, if provided without context, could deter some consumers from taking necessary medicines

Pros and Cons of Drug Safety Communication

- **Reason (2)** Complete information allows for a more informed and better choice
- **Pros:** More information leads to better and more appropriate prescribing and use decisions
- **Cons:** Some consumers do not want to be involved or engaged in decision making, preferring to have choices made for them
Pros and Cons of Drug Safety Communication

- Reason (3) Adverse events might be avoided if health-care providers and patients know the adverse events and the steps to mitigate any serious outcomes
- Pros: Such knowledge could lead to fewer or less serious adverse events
- Cons: Some adverse events are unavoidable despite best care; communication may lead to unrealistic expectations that all adverse effects can be avoided or prevented
Pros and Cons of Drug Safety Communication

- Reason (4) Communicating drug risk information supports patient to take part in decision making
- Pros: This is consistent with trends toward patient input into health-care decision making
- Cons: Patients might give excessive weight to small risks when considering the benefits of a therapy
Pros and Cons of Drug Safety Communication

- **Reason (5)** Failure to communicate drug-risk information may undermine confidence in drugs and lead to underuse of effective therapies
- **Pros**: Communicating drug risk information can foster trust in the development, regulation, and prescription of medicines
- **Cons**: Not communicating drug risk information could lead to patients pursuing untested or unregulated therapies and thus lead to more adverse events
Challenges of Risk Communication
Sources of Drug Safety Information

- Safety Information from Clinical Trials before approval
  - Relatively small numbers of subjects
  - Subjects are highly selected
  - The causal relation of an adverse event to the drug is not always clear
Sources of Drug Safety Information

- Postmarketing Surveillance
  - Intensive monitoring through spontaneous reporting to regulatory authority and continuing epidemiological studies
  - Lack of proof of the causality of an adverse event
Content of Risk Communication

• Clear link between drug and adverse event
  • Data of the drug and event
  • Interpretation of data
    • Risk assessment
    • Clinical considerations
    • Data to support risk
  • Mitigating factors
  • Steps for healthcare providers and patients to take to reduce risks
Content of Risk Communication

- Early Communication on emerging data
  - Communicates safety information before conclusions have been drawn or approval of regulatory action
  - Safety issue could affect
    - Use of the drug
    - A vulnerable population
    - Actions can be taken by healthcare providers or patients
- Usually brief communication
  - Outline potential safety issue
  - Data to be reviewed and expected time frame of review
Resources

- To make risk communication a core activity of regulatory authorities
  - Resources to support the activity
  - Expertise to generate and interpret research findings
Crafting Messages

- Basic thought processes in decision making influence risk perception
  - People simplify
  - Once people’s minds are made up, it is hard to change them
  - People remember what they see
  - People cannot detect omissions from the evidence they receive
  - People may disagree more about what “risk” is than about how large it is

Drug Safety and Media

- Media coverage of drug safety issues:
  - Rarely reflects uncertainty
  - Use simple, straightforward message
  - Experts’ opinions may be edited for effect
- Outcome
  - Public may take away a clear message that a drug is harmful when the evidence is still uncertain
  - E.g. swine flu vaccine and Guillain-Barre Syndrome
婦打流感針後乏力 2010年11月19日

Apply Daily News

【本報訊】本港新增一名女病人注射流感疫苗後懷疑引致吉巴氏症的個案。她本月1日於私家診所接種流感疫苗後下背痛及下肢乏力，入院後情況穩定。
衛生防護中心最新一期《傳染病直擊》透露，一名41歲女子本月1日到私家診所接種流感疫苗後，出現下肢乏力及下背痛的症狀，遂於本月14日到瑪麗醫院求醫，現時情況穩定，醫院正替她進行腦脊髓炎及骨髓炎等測試。今年的流感疫苗組合，可預防H1N1豬流感病毒、甲型H3N2柏斯型病毒及乙型布里斯本型病毒，但去年接種豬流感疫苗時，曾有市民出現下肢乏力的症狀，懷疑罹患可致癱瘓的吉巴氏症，市民接種疫苗的意欲也下降。
家庭醫生鄭志文表示，到其診所接種流感疫苗的市民，較去年同期減少兩、三成，相信與今年的疫苗組合包括豬流感疫苗有關。
Drug Safety Communication

- **In Short...**
  - Provide timely, balanced information about the safe and effective use of medicines to everyone
  - Communications must be based on the best evidence
  - Partnerships with health-care institutions, professional associations, consumer groups, academia, and the pharmaceutical industry are required
Thank You